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The focus of the Medical Vanguard Project has continued to progress in the fields of telemedicine, surgical simulation, and distance education. The key areas that the annual report presents includes:

The shift from interactive video based telemedicine to non-interactive, store and forward applications that are Internet based: This switch comes from the difficulties in scheduling interactive sessions with physicians who already have tight schedules and therefore make the telemedicine consult difficult. We have launched an extensive Internet telemedicine program in two chronic illness areas, diabetes and home peritoneal dialysis from the previous efforts dealing with telemedicine support for acute care. Also reported this year is the development of a global MRI teleradiology network to support medical research of rare diseases where studies from multiple institutions, including international sites. The support of distance medical education, a comprehensive database containing pathology slides of 240 prostate surgical specimens was established at the ISIS Center. Our simulated biopsy indicates that the current biopsy protocol is suboptimal. The integration of imaging systems and surgical procedures effort is accomplished in part by establishing the technology requirements for image-guided therapies. Advanced technologies included in this report are impedance imaging and a palpation training system.

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## Executive Summary

## Medical Vanguard Project

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# Chapter 1

## Virtual Clinic for Patients with Chronic Illness
## Project Planning Document

### Executive Summary

The purpose of this project is to provide research and development services and to study biomedical applications of Next Generation Internet (NGI) technologies. The target, clinical issue, is the management of chronically ill patients with diabetes.

This chronic illness is selected because of its costly long-term care and its impact on a large segment of the population. For the purpose of experimental design, diabetes provides an excellent model, with clear surrogate markers that can be directly linked to the eventual long-term outcome. Our testbed environment is the virtual clinic, where patient data acquisition, support, interaction and education can take place electronically using a variety of networking technologies, ranging from the current Internet to the eventual NGI.

This testbed is designed to yield insights into three areas of research: clinical outcome, economic studies, and engineering prototype development. Our study will attempt to build a clinical economical model, which includes factors on procedures of care, clinical outcome, quality of care, and quality of life. Our experimental design is based on the findings of the Diabetes Control and Complication Trial, which showed that more patient interaction with providers leads to improved diabetes clinical outcomes.

We plan to provide patients with increased access to the treatment team via the virtual clinic, as compared to the current standards of care. We hypothesize that NGI-based interaction via the virtual clinic is functionally equivalent to conventional care. The NGI Virtual Clinic may further foster and accelerate the utilization of effective in-home healthcare. There may be some unanticipated benefits or additional burdens added to the patients and/or to the physicians. The third domain of research that deals with the technical elements of NGI will focus on a high performance prototype testbed that will provide insight regarding the quality of service and network management for the NGI.

## 1.0 Introduction

Healthcare is a relative newcomer to the on-line world. The potential benefits of the on-line world in healthcare are enormous, but this new world also comes with a number of significant risks. Advances in technology allow us not only to compute and communicate but also to coordinate and to interact. On-line medicine is defined as health care in a networked environment. How then can the healthcare industry take advantage of the on-line world while managing the inherent risks?

We plan to conduct research and evaluation study in three areas: clinical economics, clinical outcome, and prototype engineering development for NGI.

## 2.0 Significance and Problem Definition

Following paragraph discusses the significance of each of the planned research domains and, furthermore, identifies specific problems that we are planning to evaluate.

### 2.1 Medical Significance and Problem Definition

Diabetes is a chronic disease that affects more than 16 million Americans and is characterized by serious, costly and potentially fatal complications. Untreated diabetes can lead to blindness, amputation, heart disease, kidney disease and death. A diabetic patient who follows a required rigorous management regimen is able to lead a productive and satisfying life. However, due to the high demands of this regimen and the life-long nature of the disease, patients have a great deal of difficulty following their regimen. The degree of non-adherence to diabetes regimen tasks can vary significantly as shown below [HAR98]:

- Diet--not following meal plan 35-75%
- Insulin--improper administration 20-80%
- Blood glucose testing--inaccurate recording 30-70%
- Foot care--inadequate care 23-52%
- Exercise--inadequate amount 70-81%

In diabetes, the day to day management is performed by patient self-care. This results in episodic contact with a physician as needed. The disease, however, requires a continuous method of monitoring. The virtual clinic, by allowing frequent interaction, self-monitoring and education via multimedia information tools and data result transfer may meet this requirement. We believe that this change will lead to reduced medical visits, far more optimal disease control, and, in turn, decreased admissions and improved overall health status.

### 2.2 Significance for Economic Evaluation and Problem Definition

Fifteen percent of U.S. healthcare dollars are spent on diabetes; $100 billion in direct costs (more than any other disease) and $140 billion in indirect costs. Annually, 12,000-24,000 people with diabetes become blind, 54,000 people with diabetes require an amputation, and 20,000 people develop kidney disease requiring dialysis or transplant. The risk of heart disease and stroke is 2-4 times higher for people with diabetes and 65% of the people with diabetes have high blood pressure.

In 1994, there were 502,000 hospital discharges with diabetes as the primary diagnosis (i.e., first-listed diagnosis) and 3.5 million diabetes-related discharges (i.e., discharges listing diabetes as one of seven discharge diagnoses). Diabetes-related discharges accounted for 24.7 million days of hospital stay. In 1993, diabetic patients made almost 121 million contacts with physicians, averaging 15.9 contacts per person. The problem of staggering costs will be addressed using the clinical economical model.

### 2.3 Significance for Engineering Development and Definition of Technical Problem

Our virtual clinic requires management of many types of data (multi-modal) with many participants at many locations (multi-nodal). This type of network Quality-of-Service (QoS) must include effective management of resources such as bandwidth, delivery latency and throughput. One of the major challenges facing NGI designers in general, and application deployment (i.e. on-line medicine) in particular, is to provide a flexible and efficient way to facilitate access by the applications level to these network level QoS mechanisms. The difficulty here is threefold. First, many emerging NGI QoS specification and control mechanisms are far removed from the applications, and are only accessible through multiple system and software layers, causing inefficient utilization of NGI network resources. Second, increased application complexity elevates application level heterogeneity, causing difficulties using existing network management and resource allocation tools for NGI applications. Third, different application-level QoS requirements and network management approaches may have vastly different effects on network load and utilization.

Another source of complexity is that distributed applications must use different NGI QoS options in different ways. This is the root of the dichotomy between network-centric design and application driven needs. In order for applications to take advantage of these options, the networks' semantic differences must be reflected through the distributed application [Ahl98, Clar90]. By moving this management complexity into the middleware layers, applications can take advantage of entirely different network architectures without needing to modify their code [Sim99b].

For this project, the virtual clinic and the NGI technology are expected to converge into a responsive healthcare service distributed to the home (or any other preferred environment on the network) in an user-transparent and network-efficient manner. The clinical studies will rely on an operational virtual clinic, both with and without the specialized development of our NGI testbed capabilities. To support the clinical goals, technically, it is necessary to achieve distributed data coordination, dynamic flow control, and a significant degree of autonomous management, aimed at optimizing arrival-site (clinic application) requirements for effective service delivery on the NGI.

## 3.0 Research Goals

The global goal of this research and development application is to establish a testbed application that require NGI in managing a major chronic illness that involves health care, health education and health research. The major goals of our planned research is to provide scientifically robust answers to the following question:

- Can the use of NGI-based interface technology provide additional clinical intervention to maintain tight glycemic control and steady blood pressure management in a manner that is functionally equivalent to an office visit?
- Can the use of NGI-based interface technology be cost-effective in managing diabetes patients?
- What are the key technical performance parameters required in NGI to support the management of diabetic patients?

## 4.0 Approach to Project Design and Development

We are approaching this question from several key perspectives: (1) Significance, (2) Experimental Design, (3) Relevance to NGI, and (4) Preliminary data.

### 4.1 Significance

NGI is expected to provide ubiquitous, interactive and intelligent communication to the general population and we are interested in bringing biomedical applications to a large number of people. Diabetes is offered as a clinical platform because diabetes is one of the major national health problems in terms of its prevalence and total societal cost.

### 4.2 Experimental Design

Unambiguous, experimental design is necessary to measure the impact of NGI based health care. Such design calls for measurable outcome parameters. In the case of diabetes, the surrogate markers are well established. These surrogate markers are blood sugar level ($HbA1_C$), blood pressure and cholesterol levels. Blood sugar levels are determined by daily measurement of blood sugar and $HbA1_C$ levels every three months that reflects average long term trend. By tracking changes of these parameters, one can assess the eventual long-term outcome using the established protocol. This makes the study highly evaluable.

### 4.3 Relevance to NGI

The management of chronic illness calls for intervention at any location and at any time for many people; an ideal setting for NGI applications. Our virtual clinic model has two parts. Phase I provides the on-line care environment, supported by distributed, autonomous agents and based on pre-NGI technologies, for a controlled, clinical evaluation study. Phase II integrates the virtual clinic with the NGI testbed specifically engineered to support such on-line care. These two-part studies offer insight into the value of NGI in the clinical healthcare setting.

### 4.4 Preliminary Data

Georgetown University Medical Center has been active in a telemedicine pilot project over the past 12 months. University of Hawaii is also conducting a pilot diabetes tele-monitoring project at the Waianae Coast of Hawaii, where some of the proposed developments of clinical agents are taking place.

## 5.0 Virtual Clinic Testbed for Diabetes Patients

Patients with chronic illnesses such as diabetes suffer from long standing morbidity that may hinder motivation for self-care. The conceptual model, which underlies and frames our

hypotheses, anticipates that frequent communication, education and feedback to these patients will encourage greater self-care and a better sense of self-determination. Internet technology offers a new strategy for engaging diabetic patients by providing information exchange, emotional support, and encouraging behavioral change, as well as monitoring key treatment markers. The fact that 44% of adult Internet users are looking for health related information on the internet underscores the concept that an increasing number of people find the Internet a valuable and effective way to communicate about medical issues (BRO98). Indeed, the Internet has great potential for providing the ongoing support needed for the long-term maintenance of behavior change for people with diabetes and other chronic illnesses (McK98).

The published literature shows that a professionally moderated, behaviorally-focused discussion group has been an effective strategy for engaging people in discussion about their disease. Within the last year 78% of 19,583 actual users (with an average visit of 8 minutes) who visited the Joslin discussion groups rated participation in the discussion groups as having a positive effect on their ability to cope with diabetes. The on-line support of healthcare professionals and the up-to-date information provided about diabetes was rated by 87% of the users as most beneficial to their individual programs (ZRE99). Our pilot study at Georgetown University and University of Hawaii have also demonstrated that patients with type-1 diabetes readily interact with their health care provider by transmitting the data from their glucose monitors via modem to their health care provider for review and comment. This increased access through a simple modem was associated with maintenance of excellent glycemic control for one year. We plan to expand our experience in these projects by providing fully integrated, multi-factorial support for these high-risk patients.

To test the virtual clinic in a clinical setting, Georgetown University Medical Center will enroll an equal number of patient volunteers, each divided into a control group and a test group. Both groups of patients (conventional and virtual clinic supported) will receive the current base-line standard of care. In addition the test group will be given the virtual clinic environment on the network. It has been established that more frequent interactions with the patients will improve the outcome of diabetes management. Our virtual clinic will be shown to have the functional equivalence of the conventional clinic visit, together with the benefit of frequent, on-demand access to the medical profession using the networking technology.

### 5.1 Diabetes Standard of Care

Both study sites will adhere to the Standards of Care for diabetes treatment developed by the American Diabetes Association [ADA99]. These Standards provide target goals for blood glucose, blood pressure control and lipid levels. The Standards also outline frequency of key exams such as blood tests, eye exams, foot exams, dietary review and others as needed. The standard care group will receive care via the standard outpatient office setting. The frequency of office visits is determined based on health condition of the patient.

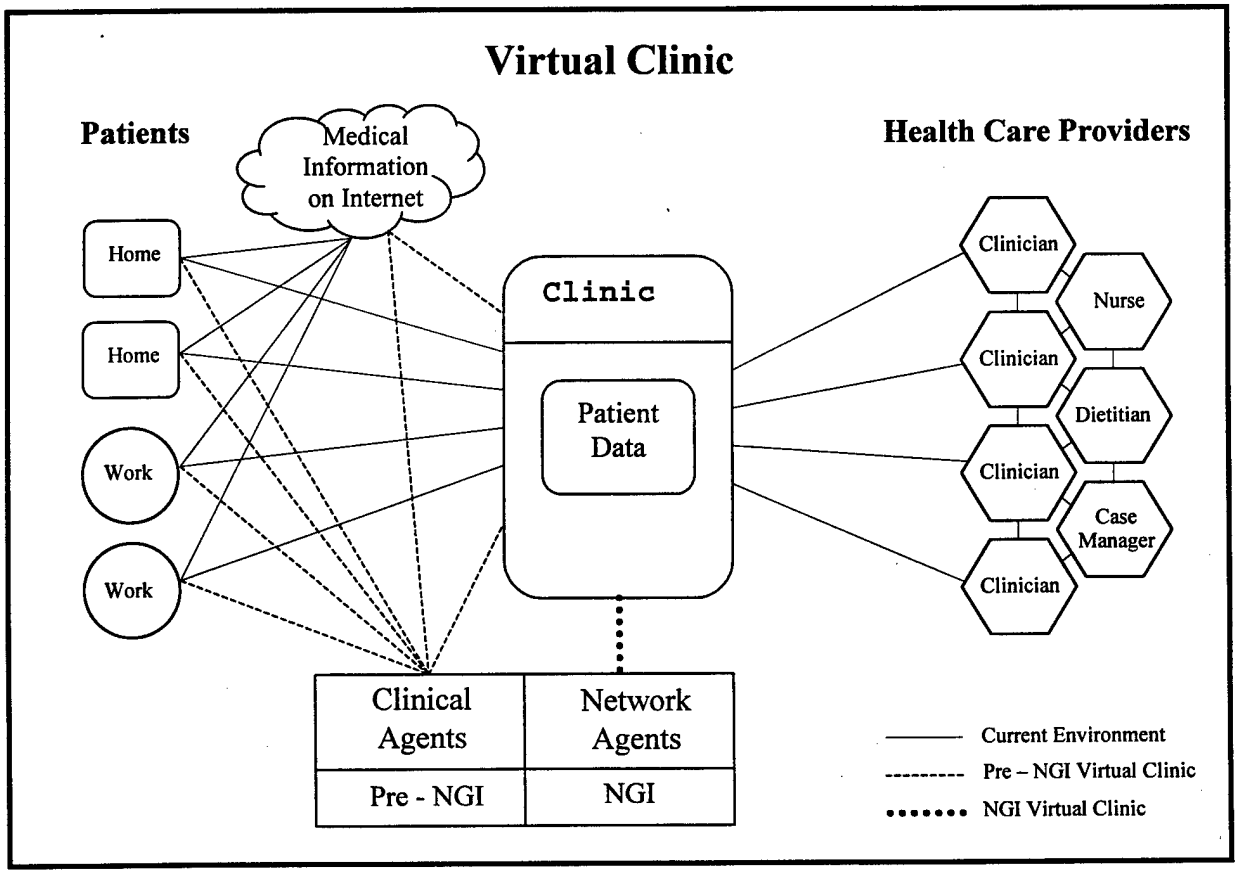
### 5.2 Virtual Clinic; Pre-NGI Environment

The virtual clinic will be developed in two phases; (1) Pre- NGI platform, and (2) NGI Platform. Pre- NGI testbed will be accomplished during the first twelve months into the project while NGI testbed will require twenty-four months of developmental effort. Clinical economical analysis will be based on the Pre-NGI testbed as discussed in subsequent sections.

The Virtual Clinic is an on-line environment that emulates the event of an office visit to the physician. The major difference is that the encounter will be on-line and all medical data relevant to the patient's case, including vital signs taken at the office and lab testing data, will be brought together (as if it is a file for the physician). The diabetic patient will be expected to wait at the Virtual Clinic, but will be fed with relevant and customized information to better enable self-care. The patient specific data will be consolidated and integrated at the physician's workstation and screened by the case manager (or the office team). The physician comes on-line and visits with the patient individually after all the preparations (including data files) and triages are complete.

The development of the Virtual Clinic relies on a collection of autonomously executable agents all working collaboratively to make the Virtual Clinic a dynamic on-line environment operating just like a real office visit encounter. Agents assisting patients include automatic monitoring, charting, feedback and alerts, data coordination and management, as well as individual protocol management. Another collection of agents provide the functionality of an efficient physician office by performing patient data screening and triage, record and readiness review, and scheduling for the on-line patient-physician encounter. These clinical agents will be incorporated into the NGI virtual clinic.

### 5.3 NGI Virtual Clinic = Virtual Clinic + NGI Environment



The second phase will be the NGI Virtual Clinic, an integration of the operational Virtual Clinic with our networking agents and the NGI testbed. This part of the work is more NGI technologically oriented, rather than clinically oriented, by focusing on NGI technology validation and testbed prototyping. A small number of patients and other volunteers in Washington metropolitan area (provided with multi-media workstations and NGI networking) will be involved in validating the prototype NGI testbed.

By late June 1999, Georgetown University Medical Center will have direct access to the Abilene network. The Abilene network is part of the Internet 2 project. According to the current schedule, by this fall the Abilene network will deploy the QBone architecture. QBone provides an interdomain testbed for differentiated services, including Bandwidth Brokers (BBs) for admission control decisions. Furthermore, QBone supports an integrated measurement infrastructure, with hooks to support end-to-end debugging and auditing. The QBone plan is to share both active and passive measurement data amongst the participants. Active measurements result from user injections of specific types of traffic for measurement purposes only, while passive measurements relay on "naturally occurring" packets arising from application usage.

Our testbed will be developed over the Abilene network and will take advantage of the differentiated service QBone architecture as soon as it becomes available. By using Abilene and currently available router and host interface technology, each node directly connected to the backbone will be able to allocate a dedicated virtual circuit of up to 25 Mbps.

## 6.0 Clinical Economic Evaluation

The Virtual Clinic is an interactive network platform that allows on-line interaction between patients and care providers to communicate and exchange other resources including educational materials, quality assessment and disease monitoring.

The objective of this study is to demonstrate that Virtual Clinic interventions can improve quality and lower the cost of diabetes management.

We hypothesize that the Virtual Clinic will improve the clinical and economical outcomes by providing more frequent interactions.

### 6.1 Aim

This aspect of Project Virtual Clinic is to develop a clinical economic model, quantifying the impact of the NGI network on patient quality of care and cost in managing diabetic patients. We offer three specific aims:

- Determine the impact of the Virtual Clinic in terms of access.
- Determine the impact of the Virtual Clinic in terms of quality of care.
- Determine the impact of the Virtual Clinic in terms of cost.

## 6.2 Approach: Clinical Economic Model

In this application, access refers to the patient's access to clinic that can provide a variety of diagnostic services, treatment, information, education and other related support activities. It also encompasses care providers access to patient information as well as any other relevant information in the network environment. In this section, we describe our methodology for assessing the impact of increased access to on-line medicine on the quality of care. We will measure quality of care issues as follows:

- Measures of Processes of Care:
  - (a) Frequency of medical events
  - (b) Duration of clinic visit time
  - (c) Frequency of clinic visits
  - (d) Patient adherence with prescribed treatment regiment

- Measures of Outcomes of Care:
  - Clinical Outcomes
    - (a) Blood glucose level and HbA1c
    - (b) Blood pressure level
    - (c) Cholesterol level

  - Preference Based Outcomes
    - (a) Quality of life (health status, patient preference)
    - (b) Patient satisfaction

We will conduct a cost-effectiveness analysis from the provider and payer perspectives, assessing changes in patients' health status in association with costs to providers and payers. Conventional care will be defined as whatever care an individual patient ordinarily receives, and whatever self-care processes in which the patient ordinarily engages. The control groups will receive currently defined standards of care of clinic visits (see Section 5.1). The experimental group will be provided with currently defined standard of care and additional care provided via the Virtual Clinic.

The relatively small sample size during this phase of the project will make a full-scale cost-effectiveness analysis difficult. Despite our inability to conduct a formal CEA, we anticipate that limited evaluation of the cost-effectiveness of this intervention will allow us to estimate: 1) the fixed and variable costs of the different components of the intervention; 2) the incremental benefit of the intervention in delaying the progression to complications; and 3) the relative costs and savings to payers associated with health services utilization in both control and experimental conditions.

## 6.3 Cost Model

Costs will be calculated from different perspectives: from the viewpoint of the patient, caregiver, physician, payer, or society. Although the Virtual Clinic may be expected to improve quality, it may also reduce costs. There may also be transfers of costs, such as higher costs of

clinic but lower costs of hospitalizations for patients who have fewer complications.

We will assess both the direct costs to providers of the experimental intervention and the costs to payers in the form of health services utilization. For providers, we will study both direct and indirect (e.g., resource or opportunity) costs. These include capital expenses such as the cost of equipment, any development costs (hardware or software), fixed line charges, and any modifications of existing infrastructure or physical plant. Given the rapid rate of change in telecommunications and information technologies, such costs will depreciate over a four-year period. In the case of the purchase of equipment that may be used for other non-intervention purposes, we will estimate the percentage of time directly attributable to the intervention, and use this cost in our economic calculations.

Variable (operating) costs include maintenance, variable telecommunications charges, personnel, training, supplies, utilities, and other costs associated with the operation of the systems. This will include additional time required of providers in association with new processes of care introduced by the intervention (e.g., patient education, and review of patient data). Cost of clinic visits, telephone calls and any other direct cost will be recorded for the control group. These costs are not inconsequential. However, we anticipate that, given the significant amount of money spent on conventional care for the management of chronic conditions, over a longer period of time, once capital costs are recovered, the more significant economic impact of a medically successful intervention would be observed in a decreased utilization of services, and a delaying of more expensive, resource-intensive services (i.e., dialysis).

Data regarding services received will be obtained for each patient at three-month intervals and at the end of the study period. We will obtain cost data directly, but if unavailable, we will identify and calculate the number and intensity of specific services provided to each patient during the course of the study. Analysis of costs then will be conducted whenever possible using a unit-of-service metric, such as the Resource-Based Relative Value Scale. The specific health services from which we will obtain data include hospital admissions, emergency department visits, hospital length of stay, (office) visits, home health care services, home health care length of stay, type of home health services provided (e.g., skilled nursing, physical therapy), cost of diagnostic procedures, dialysis, medications, and lab work. Future costs and effects will be discounted at a rate of 3% per year.

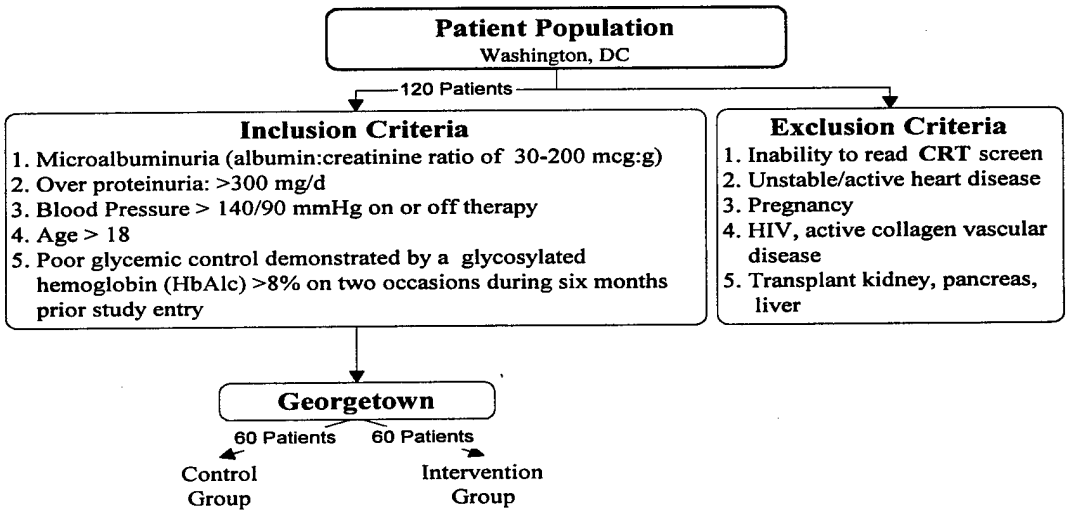
### 6.4 Method: Data Collection

Experimental data will be collected through several means. Most of the clinical data will be captured by the Virtual Clinic automatically and other data will be captured through surveys and patients' interaction with the Virtual Clinic.

One of the fundamental issues in experimental design is the number of patients under study. We carried out calculations assuming an effect size of 0.4, one retest, and an even more conservative alpha = 0.005. It is possible to detect a difference between or within groups with 1-beta = 0.75 using a sample of 40 subjects per condition, 1-beta = 0.87 with a sample of 50 subjects per condition, and 1-beta = 0.93 with a sample of 60 subjects per condition. With *two* retests, between-group comparisons would have the same power, while within-group

comparisons would have 1-beta = 0.87 for groups of 40 persons and 0.96 for groups of 53 persons each.

Given a relative high prevalence of noncompliance in the diabetic population, we assume about a 33% rate of attrition over the course of the study. We therefore need to begin by recruiting about 167% of the subjects required for acceptable power. With our assumptions regarding effect size (0.4) and a conservative decision level (0.005), with one retest, 44 subjects per group would provide power = 0.80 for both between and within-group comparisons. With two retests, between-groups power would remain the same at a sample size of 44, and would increase for within-groups comparisons. We therefore plan to accomodate a minimal sample of 45 persons for adequate power. Considering a 33% attrition rate, this means we would need to have 60 persons per group, or a total of 120 individuals enrolled in the study.




### 6.4.1. Access Data Collection

Data about access information will be measured at each session and entered into the database under the patient's folder. Automatic data collection will include initial consultation start time, end time, etc. The automatic data collection will also include the ability to determine the amount of historical information accessed as well as the type of data retrieved.

### 6.4.2 Quality of Care Data Collection

Quality of care as previously described in terms of processes and outcomes of care will be determined by applying these instruments:

- Processes of Care Evaluation Instruments will measure compliance with established

standards of care and frequency of medical events.

- Outcomes of Care Evaluation Instruments will measure clinical based outcomes such as HbA1c, blood pressure, cholesterol levels and preference Based Outcomes Quality of Life Measurements (SF-36) and Patient Satisfaction ( PSQ-18 survey).

### 6.4.3 Cost Data Collection

Costs that will be collected based on data collected for hospitalization costs, inpatient physician billing, medication costs, clinic physician costs, costs of other providers in the clinic, and diagnostic tests and procedures.

Other costs may be included later, but the aforementioned costs are those generally included in a large number of cost effectiveness and other clinical economic studies previously carried out.

## 6.5 Data Analysis

Descriptive statistics will be computed as a further check on data integrity, and to characterize the sample and outcomes. Costs per-patient of both the treatment and control interventions will be calculated and compared. In addition to overall costs per-patient, we will attempt to disaggregate these costs into the expenses involved in individual processes of care. Other outcomes will be analyzed by means of risk-adjusted analysis of covariance (ANCOVA) or ordinary least squares regression models, as appropriate to the data and the analytic question. If it turns out that one treatment condition is both more effective and more costly than the other, we may analyze the data using the incremental cost-effectiveness ratio, which is the ratio of incremental costs over the denominator of incremental effectiveness. However, we may be limited in our ability to do this by the small sample size.

In spite of the randomization of participants to one or the other condition, the small sample size poses certain analytic difficulties, which will necessitate the use of stratification or statistical risk (case mix) adjustment of outcomes. The small sample size also sets a limit on statistical power in this Phase II study, so that between groups, comparisons will be held to a minimum in order to minimize inflation in the experiment-wise error rate. In order to address this potential problem we will use multivariate techniques when possible, and use the Holm method (an alternative to the Bonferroni correction) for determining more conservative levels of alpha.

Although, as discussed above, we will be unable to conduct a rigorous, full-scale cost-effectiveness analysis, we will incorporate cost data, quality of life data, and health outcomes into a model that will permit sensitivity analyses. For each variable, we propose to use the upper and lower 95% confidence limits for that variable as substitute values, holding all other variable values constant, in order to determine a range of possible variability in outcomes due to changes in that variable. Should there be sufficient data to meet the assumptions of the techniques, we will also utilize multivariate sensitivity analyses.

Finally, we will attempt to study different patient-level intermediate (process) outcomes and their influence on the clinical endpoints and cost-outcomes. Thus, for example, are there

certain activities in which some patients engage that improve adherence and hence reduce the incidence of complications?

## 7.0 Clinical Outcome and Patient Satisfaction

Landmark studies such as Diabetes Control and Complication Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) demonstrate that tight glycemic control and aggressive blood pressure management reduce the risk of complications among patients with diabetes. These studies also demonstrate, however, that patients require intensive support from providers in order to follow the rigorous treatment protocols necessary. Intensive diabetes care with monthly office visits is difficult to provide, primarily because of its high cost. The virtual clinic may offer an alternative way to provide intensive social support of rigorous clinical protocols at an affordable cost. We intend to evaluate this basic hypothesis providing interactive additional support,

### 7.1 Patient Outcome Study

Aim: To demonstrate that virtual NGI "visits" can provide patients with support for maintaining tight glycemic control and steady blood pressure management in a manner that is functionally equivalent to office visits.

Hypothesis: Because patients receive greater support from providers than is available in the current standard of care, their diabetes self-care and their outcomes improve using affordable NGI-supported technology.

### 7.2 Approach to the Project: Conceptual Model of Online Care

Patients with chronic illnesses such as diabetes suffer from long standing morbidity that may hinder motivation for self-care. The conceptual model, which underlies and frames our hypotheses, anticipates that frequent communication, education and feedback to these patients will encourage greater self-care and a better sense of self-determination.

### 7.3 Methods: On Line Diabetes Care Using NGI Capabilities

Goals of diabetes management are to:

- Achieve and maintain a HbA1c level of 7% or less.
- Achieve and maintain a blood pressure of 120/80 mm Hg or less.
- Achieve and maintain LDL cholesterol of 100mg/dl or less.

These parameters are being utilized as surrogate markers in our experimental design. Prior studies [GAE99] have demonstrated that intensified multifactorial interventions with the above target goals is associated with reduced incidence of microvascular complications. The virtual clinic will be designed to enhance the following self-care objectives, as listed below:

- Perform self-monitoring of blood glucose at least twice per day and adjust diabetes medication with guidance from the case manager. The patient will download the blood glucose (BG) data biweekly. The case manager will review trends of the BG data

regarding the patient's weekly average BG level, frequency of hypoglycemic events, and fluctuation of the BG levels. Automated on-line consultation will be initiated if BG levels fall outside the target range. Specific changes in diet or medications will be discussed via e-mail between the case manager and the patient when necessary, based on the BG data.

- Perform self-monitoring of blood pressure. Patients will be given a home blood pressure monitoring device and will be instructed in its use. Patients will be advised to record their daily blood pressure reading. This log will be reviewed weekly by the case manager. Patients with blood pressure readings consistently above target ranges will be notified online and adjustments will be made in blood pressure medications or diet, as indicated.
- Follow and self-manage a meal plan and perform regular exercise. The dietitian and the patient will negotiate an individualized meal plan that meets the nutritional/medical needs of the patient and offers acceptable flexibility. Patients will be encouraged to perform structured aerobic activity, or to increase their level of moderate intensity activity for a minimum of 30 minutes per day. Patients will be encouraged to compare their actual eating to their meal plan by using an on-line food diary (Menu Mizar, Menu Systems, Inc, Ruffs Dale, PA). An online discussion group will be maintained and led by a dietitian. Through the discussion group, patients will ask questions and share experiences regarding food and diabetes control. The dietitian will post relevant articles and give monthly on-line classes to enhance understanding of nutritional principles. Through on-line education, patients will learn what practical and achievable eating behaviors are warranted and will be encouraged to use these tools for their own self-care.
- Maintain a positive outlook on diabetes self-care. The complexities of diabetes self-management and the uncertainty of diabetic complications produce great challenges to maintaining emotional health. Following an initial, individual psychosocial evaluation focused on barriers to self-care, the Internet will be used to establish an interactive diabetes intervention that will be uniquely valuable to the study group, user-friendly, and easy to navigate. This internet intervention will use techniques adapted from a cognitive behavioral model of therapy to help patients focus on barriers to adherence, diabetes distress, and cognitive distortions to empower patients to set realistic goals, find emotional support, and identify steps toward behavior change.

This online care intervention will have behavioral experts who will:

- Be available to offer patient consultation and facilitate group discussion.
- Develop on-line, tailored information that can address individual questions while safeguarding appropriate and necessary confidentiality.
- Use behavioral measures to help patients evaluate their own needs in terms of sources of stress, barriers to self-care, readiness to change, quality of life, and treatment satisfaction.
- Offer the latest diabetes self-management information.
- Focus on patient satisfaction and first-class service.

With both real time and non-real time, individual and group strategies, the online care patients will:

- Receive educational information and behavioral strategies about reducing stress, coping with negative thoughts and other barriers to diabetes self-care, and adhering to medical recommendations.

- Engage in a real-time, electronic, professionally moderated, group discussion focused on the educational, emotional, behavioral and familial issues important to adherence with diabetes care.
- Have password access to a non-real time, professionally moderated, interactive discussion area focused on effective techniques to change behavior and build diabetes self-management skills. This area has the capability of reading and posting messages, asking questions of another user or the professional moderators, or responding to another person's message. The diabetes educators and experienced group facilitators will also offer advice and comments based on the latest diabetes self-management information.
- Have access to a library of reference materials about the dealing with the emotional, behavioral and relational aspects of diabetes.
- Periodically complete self-scored or computer scored questionnaires that will help them evaluate their own needs in terms of sources of stress and barriers to self-care.

## 8.0 Engineering Research: Insight into NGI Technical Requirements and Specifications

The two main technical issues addressed will be : (1) Quality of Service (both clinical and networking) and (2) Network (including bandwidth and flow scheduling) Management. In addition, the development of both the Virtual Clinic and the NGI testbed will provide frequent links to on-line patient privacy and data security enforcement mechanisms.

### 8.1 Distributed Agents

Distributed agents for the Virtual Clinic are divided into two classes -- clinical agents and network agents. Functionally, clinical agents provide for patient monitoring, data coordination, protocol customization, encounter session screening and scheduling, etc. Network agents manage and configure resources, and also provide an interface to NGI runtime network layer protocols to the clinical agents. These agents serve different purposes, as detailed below.

### 8.2 Clinical Agents: (Pre-NGI Testbed)

To coordinate and manage patient data monitoring and to conduct electronic patient-physician encounters according to individualized need, for example in terms of automatic triage and feedback based on patient data (captured by the patient, laboratory, pharmacy, and/or insurance). We are already in the process of developing these autonomous triaging and data coordination agents, including those for patient data management and individual protocol management.

To enhance physician office productivity by coordinating the schedule of physician-patient encounters and preparing the patient's on-line visit to the Virtual Clinic environment. Agents capable of assisting the care provider's team to conduct medical record review and screening will dramatically increase the virtual office productivity. Customization, according to the patient's individual needs and preferences during the virtual office visit and patient file preparation, including checking for readiness in the clinical pathway, would also be agent-executable services offered by the Virtual Clinic.

Development of these agents, including physician response, clinical screening and scheduling, will be executed in the first twelve months of the project in order to support an on-line Virtual Clinic based on off-the-shelf distributed network technologies. These agents will be data/context sensitive and autonomously controlled, to operate in a distributed and dynamically reconfiguring network environment on both the client and the server workstations. Based on this

Virtual Clinic environment, an outcome study on its effectiveness for in-home care of diabetic patients will be conducted during the ensuing months.

### 8.3 Network Agents (NGI Testbed)

To enhance the effectiveness of patient-to-provider interaction by providing high quality data and high quality service through intelligent network QoS control and management. This effort will develop a functional NGI testbed. Here, agents will also be deployed to integrate a heterogeneous system under various network conditions with patient computers using a variety of hardware platforms, different operating systems and different application programs. Based on service requests and traffic profiles, agents can specify and prioritize end-to-end QoS requirements.

We expect this engineering development effort will require eighteen months initially, followed by a 6-month testing of the prototype of NGI testbed in a multi-workstation, multiple sites setting. A final six months of operational testing of this NGI Virtual Clinic (months 24 to 30) will provide both a design of the NGI-based Virtual Clinic and new insights into NGI technical requirements for effective in-home delivery of medical care.

Collectively as an integrated system, clinical agents can already support an operational on-line Virtual Clinic, in a rudimentary way using pre-NGI networking technologies. The infusion of network agents on the NGI testbed is expected not only push the agent and networking technology but also to enhance the capability and service richness of the NGI Virtual Clinic environment.

### 8.4 Virtual Clinic on the NGI Testbed

The integration of the Virtual Clinic with the NGI technology base is expected to harvest additional benefits. Using available Internet 2 technology, we will develop a working NGI testbed to serve as a platform for deploying, testing and evaluating the NGI Virtual Clinic. This NGI testbed effort focuses on two major issues:

#### 8.4.1 The Design and Development of NGI Network Management Techniques

Our approach to developing NGI network management is through the development of a QoS-aware agent infrastructure and communication and configuration language capable of providing rapid selection, configuration and reconfiguration of NGI network service types and different user platforms. The infrastructure, designed to operate as a type of middleware layer, will expose on-line medicine applications to a variety of QoS options by providing QoS-drill techniques and automatic communication software configuration for multicasting, and service and QoS parameter selection. Drill-down methods expose the application to different network and transport layer QoS options [NSF97].

#### 8.4.2 Understanding and Evaluating Quality-of-Service Requirements for Virtual Clinic

Initially we will identify and develop agent-based techniques to automatically determine appropriate QoS levels, including bandwidth requirements and multicast capabilities. We will conduct a careful performance and workload analysis on our testbed. These models will be used to test the scalability of the management infrastructure, the effect of different NGI QoS options

on the application and the network performance, as a way of injecting traffic into live networks for testing and evaluation purposes.

### 8.5 Network Management for the NGI Virtual Clinic

This task investigates NGI management and collaboration infrastructure through the development of a new, Web-oriented configuration language (OC-XML), agent-based middleware design methodology, and QoS selection and evaluation procedure. We expect collaboration-oriented NGI applications in a distributed healthcare setting will run within heterogeneous networks using a variety of hardware platforms. To support such needs we will develop a network management infrastructure using a system of communicating autonomous agents.
Within Virtual Clinic, the major advantages of an agent-based approach are:

- The ability to isolate independent and cooperating NGI and its application component functionality into multiple agents.
- The ability to design and implement an agent-based and user-friendly NGI configuration language.
- The ability to develop a mobile and reusable code.
- The ability to carry out careful performance and workload evaluations of different but interacting Virtual Clinic components in order to gain further insight into NGI requirements and capabilities.
- The availability of a natural abstraction mechanism for modeling large systems of interacting machine and human users.

Virtual Clinic applications will specify, access and control NGI services and QoS options by writing, modifying, exchanging and loading QoS-configuration pages. These pages are written using a proposed QoS-enabled XML-based markup language dubbed "OC-XML", for Virtual Clinic extended Markup Language. OC-XML will be used as the basis to develop an Agent Communication Language (ACL) allowing clinical and network agents to interoperate. All agents will be able to dynamically produce, modify and exchange OC-XML pages. This will be done in response to changing application needs, QoS capabilities, and as a result of inter-agent communication. We wish to emphasize our belief that the OC-XML approach will be useful for NGI-enabled agent-based applications in general and not just for the Virtual Clinic. This approach means that agents can be "plug-and-play", without seriously disrupting the system operation.

The Collaboration Switch and OC-XML specification will be incorporated into the network management and flow scheduling software that caters to the dynamic Virtual Clinic application. This agent-based software will be developed using the Constrained Resource Planning (CRP) methodology of D. Y. Y. Yun. This resource management tool (both the CRP methodology and its execution engine) has been successfully applied to more than 40 different application domains over the past 15 years, including a network flow management and cooperative agents.

A complex collaborative NGI application as the Virtual Clinic, with simultaneous patient-physician interaction sessions and multi-modal communication requirements, requires such an intelligent agent approach to manage the design and deployment of such systems. By upgrading the agent-based Virtual Clinic environment into the NGI-based Virtual Clinic (from

month 12 to month 18), the next generation Virtual Clinic application will be tested for system performance in the ensuing six months. The following six months (24 to 30) will be devoted to realistic Virtual Clinic application testing on the NGI testbed in the form of a multiple-site clinical emulation. The results of this two-phased testing will not only clarify application requirements in both clinical and technological settings but also generate valuable insight for expansion into a widely used healthcare application system on the NGI, after the benefits are proven.

### 8.6 NGI Quality-of-Service

Our research in NGI QoS involves two different but highly related areas. The first understands how the agent-based system can effectively use our ACL to write and modify OC-XML specifications that efficiently utilize NGI QoS options. The second is how to validate and evaluate the impact of the Virtual Clinic communication Infrastructure on NGI. We believe that the impact of answering these two questions will result in a greatly increased understanding in the future deployment of NGI services, particularly the home monitoring healthcare delivery system like the Virtual Clinic proposed here.

### 8.7 NGI Virtual Clinic Validation and Evaluation

The operational on-line Virtual Clinic using pre-NGI technologies will be validated during month nineteen to month thirty in a controlled study, as described already. The NGI Virtual Clinic, representing an integration of all the Virtual Clinic capabilities and the NGI Testbed developed during the first twenty-four months will also be put under careful evaluation for six months. Unfortunately, this enriched NGI Virtual Clinic environment will not have sufficient time for a controlled randomized clinical study as the other case. The insight gained from this validation/evaluation effort will be carefully compiled and analyzed to benefit the future development of this Virtual Clinic concept and the continuing deployment of NGI technology for the delivery of medical services.

### 8.8 Scalability of the NGI Virtual Clinic

The Virtual Clinic and the NGI Testbed is expected to converge into a new responsive service distributed to the home (or any other preferred environment on the network) in a transparent manner. The clinical studies are designed to rely on an operational Virtual Clinic for proving the value of home healthcare delivery, independent from the specialized NGI Testbed aimed at a more effective service delivery mechanism. As the anticipated positive clinical outcome grows and the NGI technology/infrastructure matures, a scaled-up vision of an industry-wide in-home healthcare supported by a broadly capable NGI becomes increasingly intriguing. Thousands of homes would be "wired" with care and support from multiple virtual clinics in a geographic region, metropolitan or rural. Nationwide integration and linkage could also enhance population mobility (even for the chronically ill) to support nomadic behavior (with portable, networked monitoring devices), thereby improving patient's quality of life and work force productivity.

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# Chapter 2

# Telemedicine for Hemodialysis

# Project Phoenix

## 1.0 Introduction

One of the major difficulties in assessing the impact of telemedicine is in finding appropriate measurable parameters that can be directly linked to patient outcomes. The study of hemodialysis provided us with such a parameter for studying telemedicine's impact within that specific specialty. The mortality rate of dialysis patients can be directly linked to the dose of delivered dialysis. It is quite difficult to maintain a tight regiment of dialysis over a long period. The patients must be connected to a dialysis machine several hours a day for three or four times a week. Quite often they refuse to come to be dialyzed or disconnect themselves from the dialysis units earlier than prescribed. When these events happen the possibility of complications and death can increase dramatically. Our goal is to reduce these medical complications using telemedicine interventions.

Using multimedia telemedicine, we have been following dialysis patients for over one year with a weekly "telemedicine visit" in addition to weekly physician visits, in an attempt to maintain compliance with the dialysis schedule, in addition to comprehensive medical consultation. Transmission of images and data is achieved with T1 lines from the clinic to the physician's office or home. The telemedicine session uses electronic patient folders containing relevant medical details, digitized X-rays, lab values, etc. We are able to achieve high quality videoconferencing, capture still or video images, record remote stethoscope sounds, capture local or remote data (laboratory values, dialysis machine parameters), and modify the medical record. Our goal is to increase the quantity of delivered dialysis, and thereby improve quality of life, patient satisfaction, and reduce costs of medical care, at the same time maintaining patient confidentiality.

Appropriate measures to ensure data integrity and patient confidentiality have been integrated into the study. Questionnaires are also utilized to measure on an ongoing basis (quarterly), quality of life, patient satisfaction, while a weekly questionnaire captures any medical event taking place. The system and procedures we have employed are accepted enthusiastically by patients and staff alike and have aided in patient management.

The hemodialysis study compares two sites on the impact of telemedicine on patient outcomes. One site is the test site where telemedicine is employed and the other where telemedicine is not used. Instruments for measuring patient satisfaction, quality of life, cost data acquisition, and security have been used during the study. To ensure patient

privacy in the open dialysis unit, we have used a patient microphone/earphone headset, which is inter-changeable with standard microphone/speakers or stethoscope into the telemedicine system. Hemodialysis data (automated blood pressure, venous pressure, arterial pressure; transmembrane pressure, blood flow rates; dialysate flow rates, conductivity, and temperature, ultrafiltration rates, and sodium delivery) is downloaded from the dialysis machines. We have developed a web-site based teaching program for patients regarding the security issues in our telemedicine protocol. We plan to expand this as a general teaching tool about kidney disease, dialysis, and telemedicine, with links to relevant web-sites for patient education.

This report has three parts; 1) clinical and technical infrastructure, 2) data security and confidentiality and 3) ) clinical economic evaluation.

## 2.0 Clinical and Technical Infrastructure

To better understand the distinctions between telemedicine and face-to-face interactions, we have studied and compared interactions between three contexts: face-to-face communication at the Georgetown site, face-to-face interaction at Union Plaza, and telemedicine interaction at Union Plaza. The study took place over three stages: development of an appropriate coding scheme, coding of interactions, and data analysis. We are currently entering the third stage of the study and offer some preliminary results.

### Stage 1: Development of an Appropriate Coding Scheme

After six months of observing doctor and patient interactions within face-to-face settings and telemedicine settings, we created a coding scheme that documented types of interactions between the doctor and the patient. After several iterations of the coding sheet, we settled on including interactions that included discussions of the following: social/non clinical topics, medication refills, access problems, change in dialysis, referrals to other specialists, medication changes, medication orders, travel-related concerns, labs and reports, patient complaints, family discussions, confidential discussions, and patient education. We also coded special situations like physical checks, physician interruptions, times when the patient refused to interact, and technical problems. Finally, we tracked consultation time.

### Stage 2: Coding of Interactions

We trained three coders in the use of the coding scheme. The coders maintained an inter-rater reliability of .95 indicating close to complete agreement on coded items. Basically, if the interaction took place, that interaction was coded as a 1. If it didn't, it received a 0. A section was added for the coder to include anything that took place that did not fit into the coding scheme. A total of 147 patient encounters were coded between May, 1998 and March, 1999. Fifty-one were face-to-face encounters at Union Plaza, forty-seven were telemedicine encounters at Union Plaza, and forty-nine were face-to-face encounters at Georgetown University Medical Center. All patient encounters were coded using the same physician.

**Stage 3: Preliminary Findings**

Using a T-test, we compared the means of the total interactions at Georgetown (face-to-face) with the total interactions at Union Plaza (face-to-face). We found no significant difference in the total interactions at these two locations (df=1, 98, t=-.943, p>.05). In comparing Georgetown patient encounters (face-to-face) with Union Plaza telemedicine encounters, we found no significant difference between the sum of all interactions between the two locations (df=1, 94; t=-1.894; p=.06). Although not statistically significant at the .05 level, perhaps with a larger sample size we may be able to detect a difference. Similarly, when running a Paired Samples T-Test, we found no significant difference between the face-to-face patient encounters at Union Plaza and the telemedicine encounters at Union Plaza (df=1,97; t=1.202, p>.05). We are currently investigating individual sets of interactions to explore possible differences in patient encounters during the two types of conditions.

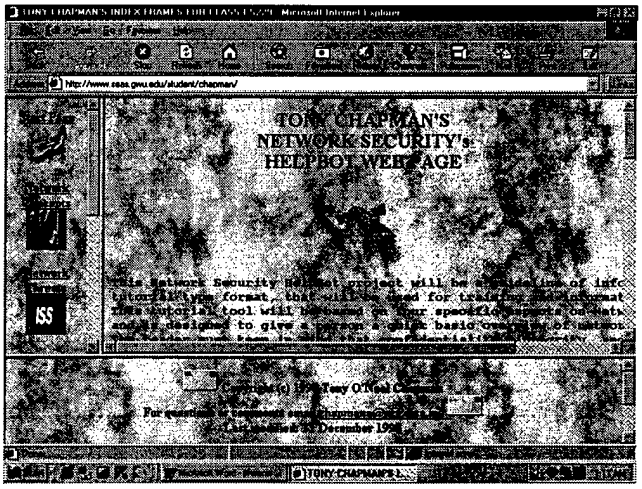
## 3.0 Protecting the Security and Confidentiality of Patient Information

Progress continues with the implementation of a firewall and secure remote access technology for the ISIS Local Area Network as reported in last quarter's report. While installation is not set to begin until June 1999, preparation for the new secured environment is underway. This includes evaluating all the existing computers on the ISIS LAN and the determining the levels of security required for each. Although not purchased under the auspices of Project Phoenix, the firewall constitutes an aspect of the Security Management Plan developed to maintain the security and confidentiality of information from patients participating in Project Phoenix. When adequately protected from untrusted networks such as the Internet, Project Phoenix will archive patient data on a magnetic tape storage device in the ISIS Center. The firewall will protect this silo as well as other assets on the ISIS Center LAN. The secure remote access technology will permit Project Phoenix investigators with appropriate access rights to consult patient data in the silo from remote locations.

HelpBot was evaluated and improved to enable users faster and easier development of computer security educational Web sites using the tool. The evaluation and improvement process involved putting HelpBot to real tests by providing it and its documentation free of charge to users to create their own Web sites for computer security related topics. The users were students in the Computer Security class at the George Washington University in the fall of 1998. The students were given an overview of the attributes of HelpBot and its applicability. A group of students decided to use HelpBot in their final course projects.

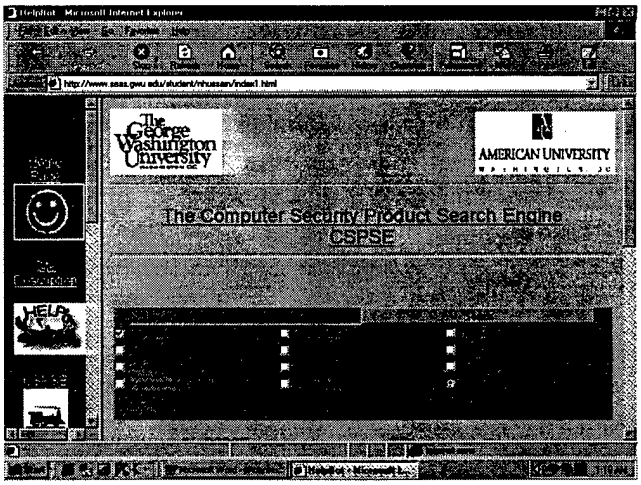
Some of the students continuously reported on their problems and difficulties and the on-line help document was improved continuously based on these comments.

Examples of students' uses of HelpBot include using HelpBot to create an educational Web site for computer security.



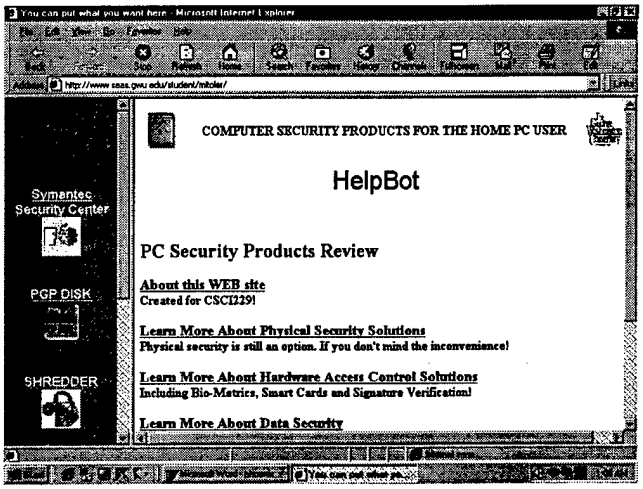

http://www.seas.gwu.edu/student/chapman

Using HelpBot to create a search engine that could be used to search for security products over the Internet.




http://www.seas.gwu.edu/student/nhussain/index1.html

And using HelpBot to present an evaluation of different computer security products available on the market.




http://www.seas.gwu.edu/student/mltoler

Later, an evaluation form was created to identify any problems with both the on-line help document and the HelpBot tool itself. It was posted on the class forum and sent by e-mail to students known to be using HelpBot.

The form can be found at:
http://www.seas.gwu.edu/classes/csci229/HelpBot/EvaluateHelpBot.html

The results from this were used to produce the improved version of the help document.
The evaluation form also contained questions intended to test the satisfaction of the users with the tool.

The users responding to the questionnaire were 5. All respondents were males. They all reported that they use computers very often. Two of the participants have prior experience in developing Web site material and the others had no prior experience in doing so. The users used different hardware and software platforms to create their Web sites.

At first, the users found difficulty using HelpBot due to problems with the help document. As the feedback from the users indicated, the users disagreed about the helpfulness and organization of the on-line help document. However, all users agreed that the tool itself was easy to use and that the templates were nicely designed.

Based on the results found in the evaluation and on the feedback throughout the semester many changes were made to the help document. All the users agreed that once they have understood how to use the templates the task became easy.
When the users were asked what changes they would make if they were to redesign the templates, all respondents agreed that they would not change anything.

The results also indicated that 3 out 5 of the developers were first-time Web site developers. Yet, the 3 developers all agreed that they found the tool very easy to use, will consider using it again, and will recommend it to others.

Moreover, none of the participants have ever used similar tools. The 2 developers who were previously exposed to Web development tools were informally asked if and why they would prefer to use HelpBot instead of other tools. Their replies were both based on the fact the output is different. The sites developed using HelpBot look better and are more organized. Such finding indicates the importance of embedding generally accepted user interface guidelines in products produces using other development tools; thus, relieving developers from the responsibility of design considerations and allowing for higher quality more accessible Web sites to be developed.

Our recommendations for improving the tool include, but are not limited to, further testing of the tool on more subjects. The cohort of subjects must be randomized and must be chosen from different educational backgrounds in order to give better indications whether the above conclusion holds true for people from different disciplines.

We also recommend that the tool be used in other disciplines to create Web sites for purposes other than computer security related projects.

Further improvements to the document may include animated demonstrations of the steps needed to create a Web site using HelpBot. Also, links to public space free script Web sites and graphics may be added in a supplementary section in the document.

## 4.0 Clinical Evaluation

### Sample Selection and Descriptive Statistics

The data collection phase of this project began in January 1997 and ended in January 1999. During this period, approximately 73 patients participated in 1,134 kidney dialysis sessions. At a monthly session, Kt/V and URR levels were measured. A Kt/V measurement of 1.4 is the minimum clinical goal of each dialysis session and is the primary outcome measure in this study –greater values of Kt/V are preferable to lower ones.

Not all of the recorded Kt/V measurements were valid. Three factors produced values of Kt/V that were considered invalid. First, measurement error led to some extremely unlikely scores being recorded. Second, some patients, while still treated, had such advanced vascular access problems that no amount of dialysis could have improved

their Kt/V levels. Third, extreme scores are more likely for new patients (patients receiving dialysis for the first time) than for patients continuing a treatment plan of dialysis. To identify Kt/V measurements that were produced by one of these three factors, each patient's Kt/V measurement was converted to a *z*-score based on their average Kt/V measurement. Consider a patient who had an average Kt/V measurement of 1.5 and a standard deviation of 0.2 during this study. If their first dialysis session produced a Kt/V value of 1.4, their *z*-score distributed Kt/V score is -0.5.

Assuming a normal distribution of Kt/V measurements (discussed in more detail later), *z*-distributed measures have known characteristics, most importantly, fixed proportions of cases under different areas of a normal cumulative density function. In short, patient Kt/V measurements that exceeded ±2 *z*-scores were considered extreme cases –sufficiently different from average for a patient to warrant further analysis. If a patient had at least one Kt/V measurement outside of these bounds, all of their Kt/V information was examined for errors. Every extreme measurement was attributed to one of the three sources of error discussed above. This led to the exclusion of seventy-four individual Kt/V measures and the exclusion of two complete sets of patient measurements. These decisions were based on the judgement of Dr. Winchester, our clinical Nephrologist. The following table presents summary statistics for the Kt/V measurement for all the data collected, the extreme cases (ultimately excluded from the analysis), and the final sample used in this analysis:

Summary Statistics for Kt/V Data by the Type of Sample

| | Original Sample | Extreme Measurements | Final Sample |
|---|---|---|---|
| Mean Kt/V | 1.50 | 1.11 | 1.52 |
| Standard Deviation | 0.27 | 0.51 | 0.23 |
| Minimum Value | 0.05 | 0.05 | 0.62 |
| Maximum Value | 2.62 | 2.26 | 2.00 |
| Number of Cases | 1,134 | 74 | 1,060 |

The final sample consists of seventy-one patients who had 1,060 dialysis treatments. Thirty-two of these patients were women and thirty-nine were men. The 1,060 Kt/V measurements were aggregated as an average value to each patient to produce a final data set with seventy-one patients –one record for each patient consisting of their average Kt/V, gender, number and type of dialysis treatment (standard and telemedicine).

Without excluding cases with extreme values of Kt/V, the Kt/V measurement was negatively skewed and decidedly not normally distributed. While there were some extreme, large values, these were somewhat offset by a larger number of low values. It is

mostly, though not exclusively, these values that were excluded from this analysis. The final sample without regard to type of dialysis treatment is normally distributed. The standard treatment group is normally distributed, while the telemedicine group was slightly negatively skewed.

As expected, since women have lesser distribution volume of water, their average Kt/V values are greater than those of the men (1.53 versus 1.46, respectively –the difference is not statistically significant).

Because a rolling admissions process was used to enroll subjects, there was some variability in the number of dialysis treatments, and therefore the number of Kt/V measurements collected. The number of dialysis sessions for each patient ranged from two to twenty-four. On average, patients had fifteen dialysis treatments. The average number of treatments was higher for the standard treatment group than for the telemedicine group (16 versus 14 treatments –the difference is not statistically significant).

**Analysis of Standard versus Telemedicine Dialysis Treatments**

One goal of this study is to determine if there is any effect, positive or negative, of using telemedicine to treat patients with kidney problems. Results favoring telemedicine should show either the Kt/V measurements are greater on average for telemedicine patients than for standard dialysis patients, or that there is no difference in the average Kt/V measurements across these groups but that either treatment costs are lower and/or patient satisfaction is greater. The issues of cost and patient satisfaction will be addressed as those data are prepared for analysis. For this preliminary analysis we can only report on the difference in average Kt/V levels between telemedicine and standard dialysis patients.

The following table summarizes the difference in the average Kt/V levels for patients who received standard dialysis treatments versus patients who received telemedicine treatments:

Summary Statistics for Kt/V Data by the Type of Treatment

| | Standard | Telemedicine |
|---|---|---|
| Mean Kt/V | 1.55 | 1.44 |
| Standard Deviation | 0.19 | 0.20 |
| Minimum Value | 1.12 | 0.88 |
| Maximum Value | 1.87 | 1.72 |
| Number of Patients | 32 | 39 |

Without additional statistical controls, there is a slight difference in the average Kt/V levels with patients receiving standard dialysis treatments exhibiting higher levels of Kt/V. However, this difference is neither statistically nor substantially significant.

It is also possible to examine simple descriptive statistics by type of treatment, and within treatment by the gender of the patient as in the following table:

Summary Statistics for Kt/V Data by the Type of Treatment

| | Standard | | Telemedicine | |
|---|---|---|---|---|
| | Women | Men | Women | Men |
| Mean Kt/V | 1.61 | 1.51 | 1.46 | 1.43 |
| Standard Deviation | 0.19 | 0.18 | 0.22 | 0.19 |
| Minimum Value | 1.17 | 1.12 | 0.88 | 1.07 |
| Maximum Value | 1.87 | 1.78 | 1.70 | 1.72 |
| Number of Patients | 14 | 18 | 18 | 21 |

A substantial amount of the difference in average Kt/V between standard and telemedicine dialysis treatments is due to the overall high average Kt/V values for the women in the standard dialysis group.

These differences demonstrate that some of multivariate analysis is useful in explaining the difference in average Kt/V across the treatment groups. The following multiple regression model was estimated and the results are presented in the table below:

$$kt/v = \hat{\beta}_0 + \hat{\beta}_1(n) + \hat{\beta}_2(sex) + \hat{\beta}_3(treatment) + e$$

where:

| | |
|---|---|
| *n* | –is the number of dialysis treatments |
| *gender* | –is an indicator variable where 0 equals women and 1 equals men |
| *treatment* | –is the kind of dialysis treatment, 0 equals standard dialysis and 1 equals telemedicine dialysis |

Regression Analysis Comparing Telemedicine Versus Standard Dialysis Treatments

| Variable | Parameter Estimate |
|---|---|
| Intercept | 1.41 |
| | (0.07) |
| n | 0.01** |
| | (0.004) |
| gender | -0.07 |
| | (0.04) |
| treatment | -0.09 |
| | (0.04) |

* =0.05

** =0.01

*** =0.001

Numbers in parentheses are standard errors

In general, the overall model is statistically significant and explains twenty-two percent of the variance in the Kt/V measurement. However, only one variable is statistically significant –the number of dialysis treatments a patient received. For example, for each additional dialysis treatment an average patient received, controlling for the type of treatment and their gender, there is an average increase in their Kt/V of 0.01, and this increase is statistically significant. Relative to the other measures, this is the single most important variable in this model.

Examining the type of dialysis treatment, the difference in average Kt/V measurements, while controlling for patient's gender and number of dialysis treatments, is not statistically significant. In summary, the average Kt/V levels for the telemedicine patients are not significantly different than those for the standard dialysis patients.

Similarly, the gender of the patient, statistically holding constant the type and number of dialysis treatments, was not statistically significant.

**Future Analysis**

Additional analyses of these data are needed. For example, it may be that patients in the telemedicine group reach the Kt/V clinical goal of 1.4 faster then the standard dialysis treatment patients. The preparation of data is an ongoing task. The next set of data to be analyzed includes a number of socio-demographic characteristics such as marital status, education, and socio-economic status. A preliminary analysis of demographic characteristics indicates that there exists a difference in the socio-economic status of the patients at Union Plaza and the Georgetown Site. It remains to be seen if taking these factors into account will change the results presented above. Finally, we will soon be able to include summary measures of patient satisfaction. It may be possible to show that even if there is little clinical advantage, there may be greater patient satisfaction with telemedicine.

# Chapter 3

# A Multi-Center Digital MRI Network for Adrenoleukodystrophy


## Abstract

The infrastructure for a multi-center clinical trial for adrenoleukodystrophy (ALD) will be enhanced by the addition of a worldwide magnetic resonance imaging (MRI) network of clinical institutions. This network will improve the ability of the participating institutions to evaluate ALD therapies. Due to the rareness of this disorder, this network is required to provide a sufficient number of patients for evaluating ALD therapies. Consensus for the need of such a network was reached at a meeting in Baltimore in January 1999. Sixty-two clinicians and investigators attended this meeting, from all parts of the world, who share concerns about the therapy of ALD. Implementation of the multi-center MRI network for ALD can serve as a model for many other disorders.

Brain MRI and magnetic resonance spectroscopy (MRS) are the most sensitive indices for the evaluation of ALD therapies, but require the transmission of high quality images and the evaluation of these images by neuroradiologists with extensive ALD experience. Objectivity of analysis will increase by having independent scoring by two neuroradiologists who are blinded to patient treatment status. A network is being developed that allows participating sites to send their ALD MRI cases to a clinical database residing at the Kennedy Krieger Institute (KKI) at Johns Hopkins University (JHU) in Baltimore, Maryland. Two ALD experienced radiologists, one at the KKI and one in Minnesota will have the ability to summon up the MRI ALD cases in real-time on a softcopy display station and review the study. The subsequent Loes score will be maintained on-line in a database at the KKI.


## Introduction

The practice of medicine as well as the conduct of research has undergone a dramatic evolution over the last twenty years. Technological advances have profoundly modified the delivery of patient care from diagnosis through the treatment stage. Radiology has greatly benefited from advances in computers and physics over the past two decades. The conventional X-ray has been overshadowed by several digital imaging modalities including computed tomography, magnetic resonance imaging (MRI), ultrasound, and others. The images produced by these digital sources yield more information without requiring invasive procedures. As a result, the medical image has become a key element in patient diagnosis, the assessment of success of therapy, as well as a primary end point in research trials.

The digital nature of these modalities encourages and supports remote diagnosis and consultation. An expert, hundreds or thousands of miles away, can diagnose a disease by electronically sharing the medical data, including radiological imaging data, resulting in enhanced patient care. In the public health arena this can lead to major breakthroughs in the conduct of clinical trials for the treatments of rare diseases or those that are geographical in nature. A clinical trial of a rare disease performed by a single institution is difficult due to the

lack of the number of cases generated. However, due to technological advances in the movement of digital images, a multi-center clinical trial can be set in motion by identifying and integrating pockets of disease, sharing the clinical protocols, sharing the acquired digital images, and by removing biases. This type of trial can produce more meaningful results and may lead to a cure sooner, and the methodology developed here can be applied to many diseases.

**Approach**

A network will be developed that accepts MRI images from one of many participating sites and stores them in a clinical database located at the KKI-JHU. A radiologist from the KKI-JHU and one from the Suburban Radiologic Consultants (SRC) in Twin Cities, Minnesota will have immediate access to the images via a secure Internet connection. This will allow them to select and view the studies they need to see, without compromising patient confidentiality.

Each radiologist will read all the ALD studies. They will be blinded to the ALD therapy of the patient. They will have the ability to enter the resultant Loes Score on-line into the central clinical database at the KKI-JHU. The database will contain additional medical information regarding the patient.

**Methods**

While the use of MRI and MRS data to diagnose and evaluate the effectiveness of therapy is not contested, the capacity to share data from clinics in various parts of the US and other countries is severely limited. Working in a film-based world is slow, costs are high, archiving is a challenge, issues of medical data security and privacy are raised, and film does not lend itself to more advanced methods of data analysis. This paper describes the technologies required for digital image transmission and analysis in a manner that assures security and privacy, improves the ability for collaboration between research institutions, and provides real-time access to the clinical data.

The transfer of ALD MRI-MRS studies from the North American clinics, and eventually worldwide, will provide an automatic and unique mechanism to coordinate and centralize information, while greatly enhancing the capacity to collaborate. The MRI-MRS data are ideal instruments to achieve this collaboration since MRI-MRS abnormalities represent the earliest indices of nervous system involvement, and have been shown to parallel clinical progression. Unlike the clinical indices, the MRI-MRS findings (which will be read by two independent radiologists) are influenced only minimally by variations among examiners, resources, and local conditions, and small alterations in severity can be discerned more rapidly than alterations in clinical state. This permits more rapid detection of improvement or worsening attributable to therapeutic interventions and thus will increase the accuracy of therapy appraisals.

The description in this section will be confined to the image and resultant Loes score transmission and medical data privacy and security issues. The clinical evaluation of images will use the currently accepted Loes scoring system. The digital MRI network discussed in this paper permits the use of more advanced techniques, such as magnetization transfer MR, MR spectroscopy and diffusion weighted imaging. While these techniques are of great interest, they are beyond the scope of this paper and this discussion.

***Connectivity***

The American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA) developed a standard for the transmission of radiology images across a network. This standard is known as the Digital Imaging and COmmunications in Medicine (DICOM) version 3.0 standard. This standard has been widely accepted by manufacturers of radiology imaging equipment and digital image management devices like workstations.

The mechanism used to provide connectivity between the participating sites, central clinical database, and radiologists workstations is the DICOM 3.0 standard. This will provide standard connectivity and the best integration between the multiple devices. Each contributing institution may potentially have a different vendor's MRI device. Use of the DICOM 3.0 standard, provides an increased capacity to seamlessly integrate each MRI scanner with the central clinical database at the KKI-JHU.

Each participating site will electronically transfer MRI studies from ALD patients to the central clinical database at the KKI-JHU. An application, known as a DICOM Server, will be running on the central database computer. This DICOM Server will allow for the receipt of DICOM images. This is called a DICOM Storage Service Class Provider (SCP). It will also be capable of responding to queries from workstations to retrieve previously stored studies. This is known as a DICOM Query/Retrieve (Q/R) SCP. Thus, the DICOM server is capable of receiving two kinds of messages. One message transfers an image or study to the DICOM Storage SCP from a contributing site. The other message is a request for a study by a requesting site. The DICOM Q/R SCP finds the study that matches the request and sends the study back to the requesting site. The imaging modalities at the contributing sites are DICOM Storage Service Class Users (SCU) while the workstations used by the radiologists to request the studies for review are DICOM Query/Retrieve (Q/R) SCU.

The contributing sites send DICOM data over Internet Protocol (IP) utilizing existing communications options ranging from telephone lines to the Internet (Figure 1.). Connectivity to some of the sites has been established and the groundwork set for building up the ALD database. Currently studies have been received from the Medical University of South Carolina and The Brain Research Institute at Niigata University in Japan. While the database application is not completed yet, a test station is being used to verify DICOM connectivity and in preparation of the start of the collection of ALD MRI cases.

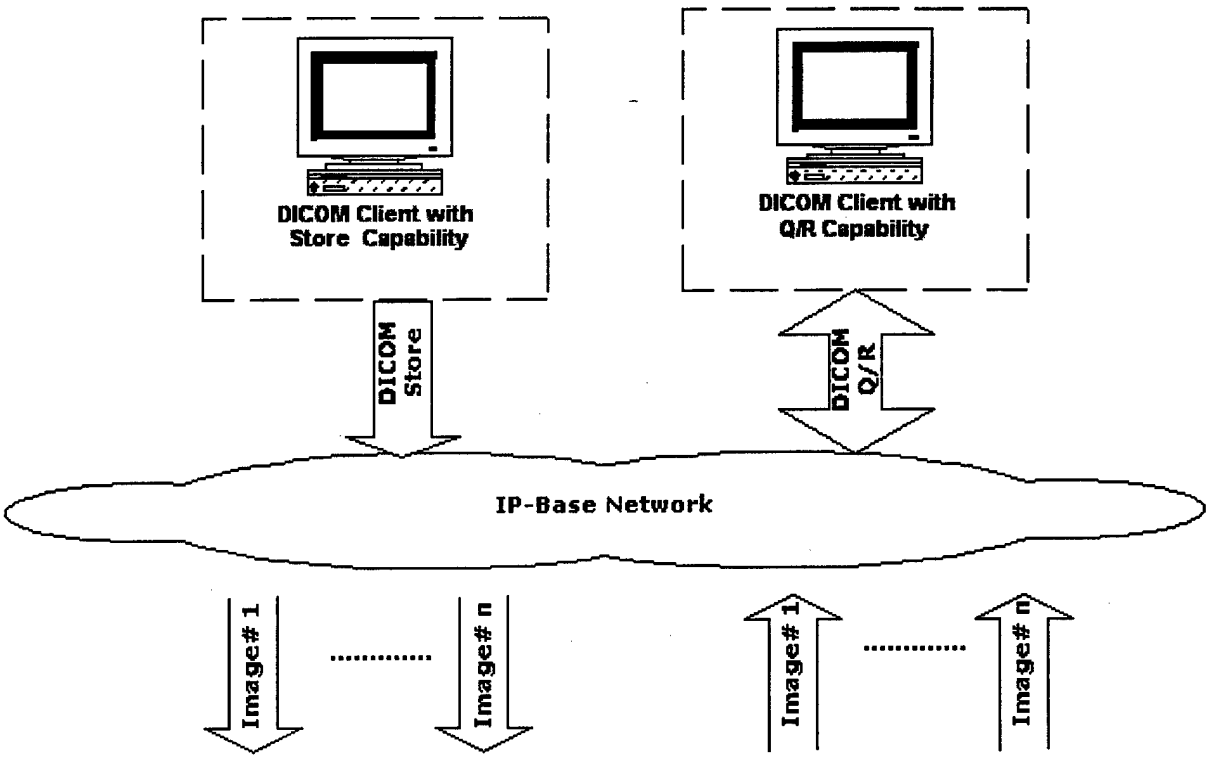



Figure 1. DICOM Connectivity

The DICOM Server will provide short and long term storage capability for national and international sites to store their images. The DICOM Server will also provide the capability to distribute images via DICOM query and retrieve functionality. Sites with Q/R SCU applications will have real-time access to information providing that they have the privileges.

At the KKI-JHU, a client-server relational database application using Microsoft SQL Server is under development to handle clinical data related to ALD patients. Researchers will be able to query the database by building powerful queries that combine data from many areas, including demographics, psycho-educational, neuropsychological, and brain imaging measurements (Figure 2.). Storing the DICOM images and resultant Loes scores for the clinical trials in this database leverages the efforts expended to develop a powerful database tool while providing easy secure access to images and other clinical medical data for ALD patients.

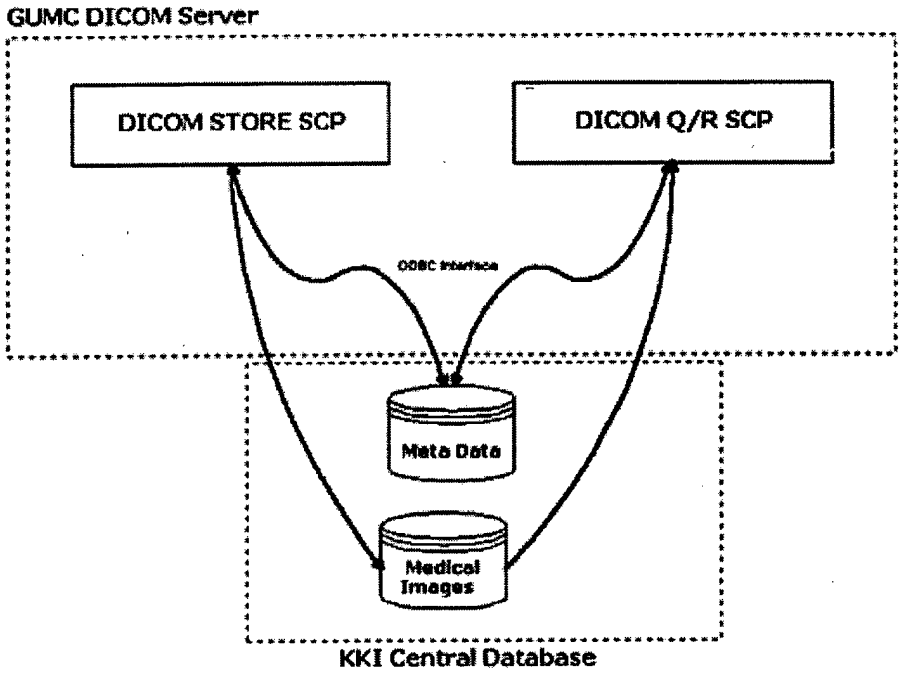



Figure 2.0 DICOM Server Architecture

***Enhanced Collaboration***

A key component of the evaluation of therapeutic efficacy is that the images be scored independently by two experienced neuroradiologists who are blinded to patient treatment status. The two sites were selected for the following reasons:

a. Johns Hopkins University and the Kennedy Krieger Institute have by far the largest experience with ALD worldwide and already have a large film archive of MRI and MRS studies. Dr. Melhem has extensive experience with ALD.

b. Dr. Daniel Loes of Suburban Radiologic Consultants at the Fairview Southdale Hospital in Minnesota is the person who devised the MRI scoring system for ALD (30) that is now in world-wide use. Drs. Loes and Melhem collaborate extensively.

This paper addresses only the transmission of images between KKI-JHU and SRC and the ability to receive immediate feedback as to the resultant score. The details of clinical appraisal are not discussed here.

The radiologists involved in this project will have access to the DICOM Server using off-the-shelf DICOM Q/R applications. Dr. Loes of SRC will use a CEMAX/ICON imaging workstation while Dr. Melhem of KKI-JHU will use a Macintosh based workstation with a high-resolution monitor and shareware versions of DICOM clients and image display software. Both of these radiologists use their workstations routinely for clinical applications and other research projects. Both workstations are capable of performing DICOM queries and of retrieving the resulting images. We will not store images on the workstations for long-term, since the radiologists will have real-time access to the database at the KKI-JHU.

The analysis and scoring of the MRI images from all participating clinics by the two radiologists will establish a standardized database that minimizes variations due to location of clinics and variations in interpretation. This proposal will provide a secure mechanism over the Web for each radiologist to document the Loes Score for a given patient. The Loes scores will be stored in the database along with the images and other information about the study. Reading of the MRI studies independently in two centers will enhance the validity of the interpretation.

***Patient Confidentiality***

To secure the data used in the clinical trials, it is crucial to safeguard the privacy and confidentiality of the patient information as well as preserve the integrity of all data. Only authorized sites will be allowed to submit information to the database. Similarly, only Drs. Loes and Melhem will be authorized to retrieve stored cases from the central clinical database at the KKI-JHU for review and to enter the subsequent Loes score into the central clinical database. Utilizing network firewalls, the central clinical database, long-term archive and the data contained within, will be protected.

Data received at the KKI-JHU as part of this project will arrive with the patient identifying information intact. Therefore, wherever possible, firewalls will be used to create virtual private networks (VPN) to protect the confidentiality of the information being transmitted. Once data has been received, the identifying information will be stripped off and a unique identifying number assigned. This will preserve patient confidentiality as well as the clinical trial for which the patient is a participant.

A VPN will be developed between KKI-JHU, and SRC. The central clinical database as well as the DICOM Server will sit behind the firewall at KKI-JHU, limiting access to the information contained in both to authorized users. While the DICOM protocol cannot pass directly through the firewall, due to limitations of current firewall protocols, a "secure hole" will be opened in the firewall to allow the packets to pass through. DICOM access to the server will be limited and the DICOM Server will further place restrictions on the DICOM services that the connecting site will have access to. This will control who is allowed to connect to the DICOM Server, and what they can do once connected- send images in to the server or request them back. Access to the KKI-JHU developed central clinical database will also be protected by the firewall. Only authorized users with access through the firewall will be able to access information in the database.

**Results**

To date, verification of DICOM connectivity between potential contributing sites involved with the ALD multi-center trial has begun. Images have been received from the Department of Radiology at the Medical University of South Carolina in Charleston, South Carolina and the Brain Research Institute of the University of Niigata in Niigata, Japan. These sites are configured to send the images utilizing the DICOM protocol. A DICOM 3.0 server is configured to receive trial images from these sites and discussions continue to encourage others involved in the multi-center trial to begin testing connectivity.

Approximately 150 ALD cases a year are expected from North America and an additional 150 cases from contributing sites around the world. Once connected the contributing sites will send all new ALD MRI and MRS data to the central database server at the KKI-JHU via the DICOM 3.0 protocol. A secure environment will be established to facilitate the receipt of this data.

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# TELEMEDICINE: Emerging e-medicine

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**Key Words** telecommunications, telehealth, teleradiology, teleconsultations, home health

■ **Abstract** This paper reviews the emergence of telemedicine and its recent expansion and use within the healthcare industry. Through this review, several examples of telemedicine within a variety of applications provide a broad context to discuss the challenges and opportunities facing the emergence of e-medicine. These examples provide snapshots of a teleradiology system used by the military, teleconsultations used in neurosurgery and hemodialysis, and home telemedicine used in diabetes care. Based on the discussion of telemedicine's history and expansion and the examples provided, a framework is offered for understanding the evolution of telemedicine applications through four stages. These stages include: (*a*) development of basic technological capabilities, (*b*) development of relevant applications, (*c*) the integration of technical applications within a complex environment, and (*d*) transformation of the operating environment. Implications for this framework are discussed.

CONTENTS

## INTRODUCTION

Technology is defined as a scientific method of achieving a practical purpose. However, technology undergoes several stages of evolution before it is adopted and applied to achieve its practical goals. As these stages evolve, the potential of the technology is unleashed. The communication age has brought with it the powerful potential for many applications that will transform the way we work, learn, and live. Healthcare is one specific industry that is witnessing an interesting transformation through the integration of these telecommunications technologies. Our population is growing older, and more people will require more healthcare, creating a huge demand on the nation's resources. The healthcare industry as a whole is at the cusp of a powerful transition as the industry faces financial difficulties caused by shrinking income, as well as the inability to cut the cost of patient care throughout the industry. Managed care is one strategy to cut the costs of care by setting limits on access and treatment costs. In the United States, more than 20% of hospitals have changed ownership in 1995 and 1996 (16). Many payers, such as insurance companies and health maintenance organizations, are also experiencing huge financial deficits. Physicians have seen a reduction in their income and an increase in their workload. Solvency of the entire healthcare system seems under attack from all quarters. Information technologies offer the promise to alleviate some of these financial difficulties by improving operational efficiency.

Healthcare is one of the most communication- and information-intense industries. Some estimate that approximately 25% of hospital operating costs are for information and communication management. With changes in the reimbursement structure of many physician payment systems, many healthcare organizations (both physicians and administrators) are seeking opportunities to improve operational efficiency. Telemedicine offers opportunities for efficient management of healthcare delivery.

The ability to transcend geographic distances is also fueling telemedicine growth. We have seen significant advances in medical technology over the past 30 years, as used in diagnosis, treatment, and prevention of illnesses. These advances have also established powerful new industries and built massive medical centers. However, these medical centers have generally been located in relatively urban areas. Although these hospitals serve patients within their commuting distances, a large percentage of patients living in rural and geographically isolated areas cannot take advantage of these advanced technologies and specialists. The idea of using telecommunication technologies emerged as a way to improve the access to and quality of healthcare at a reduced cost by overcoming the distance and time barriers between patients and care providers (8).

Telemedicine can be broadly defined as the use of telecommunication technologies to facilitate the delivery of healthcare at a distance (25). This definition includes the integration of a wide range of technologies and applications. As the telecommunications system has expanded from telegraphs to a digital global net-

work, we have begun to realize the tremendous potential of telemedicine. Advances in technology and increasing government support for telemedicine have created new opportunities for engineers, scientists, care providers, payers, and policy makers.

This paper offers a critical review of telemedicine by exploring its development through technological advances, barriers and challenges it has confronted, and new profiles of care enabled by telemedicine. Often, the clinical and business environments in which telemedicine is deployed is as important as the technology itself. Technology is simply a facilitator. This paper reviews the progress in telemedicine technology and applications within the context of the current competitive healthcare environment.

## THE EMERGENCE OF TELEMEDICINE

The existence of telemedicine can be traced to the first uses of the telephone. For example, in 1877, 21 doctors practicing in adjoining areas built one of the first telephone exchanges to allow easier communication with a local drugstore (28). Although these early efforts fit the broad definition of telemedicine (use of telecommunications technologies to deliver healthcare), modern characterizations of telemedicine have formed within the last 30 years.

Lovett & Bashshur (19) divided the development of telemedicine into three stages. The first stage was characterized by pioneering efforts with few public or private resources to support them. The second stage, between 1965 and 1973, was marked by deliberate efforts toward research and development, and these efforts received short-term federal support. The third stage continued from 1973 through 1979 and involved evaluation by interdisciplinary teams, including for the first time social scientists and specialists in medical care organization, planning, and delivery. The Space Technology Applied to Rural Papago Advanced Healthcare program, a 20-year effort, marked the intersection and application of telecommunications technology expertise gained from the space program to the problem of delivering medical care to the Papago Indian reservation. This project clarified how telemedicine applications could alleviate many of the access concerns related to healthcare delivery. Evaluations of these early telemedicine projects suggested that the technology was reasonably effective in transmitting the information necessary for most clinical uses and that patients were generally satisfied with their treatment (7, 25).

Unfortunately, the telecommunications infrastructure of the 1970s (and before) that was necessary to transmit video pictures, still images, and audio signals was scarce and prohibitively expensive (2, 3). The newness of the technology for users and experimenters resulted in inefficiencies and was met with a general reluctance to adopt (3, 13–15).

Although many of the early attempts with telemedicine could not be sustained, there are some examples of highly successful programs that use very simple

technologies. One such example is the radio medical network in Alaska. In remote villages in Alaska, health aides are trained to manage patient encounters by following strict guidelines established by the Indian Health Service, and they are authorized to administer care by the village doctors, who are located in larger towns hundreds of miles away. At a given time of the day, the health aides make radio calls to the village doctors and review patient encounters. The doctors then instruct the aides in certain treatments or other follow-up care. In serious situations, patients can also be evaluated. This system, although primitive, has improved the quality of care throughout Alaskan villages, illustrating how simple technologies can be useful in certain environments.

The 1990s have witnessed a number of developments that support the resurgence of telemedicine applications. These include the national push for information superhighways, advances in high-speed computing and telecommunication, the introduction of interactive video teleconferencing (VTC) systems, and the growing interest in integrated healthcare systems.

The most important event in telemedicine may be the introduction of VTCs into the healthcare environment. These systems were originally developed to facilitate business meetings between people separated by long distance. As costs declined and quality improved with increasing computing power, many VTCs soon captured the imagination of medical users. With little systematic evaluation, VTCs were implemented as a means of delivering healthcare. Teleradiology, although a form of telemedicine, could not be as readily launched by many for some years, owing to the exorbitant costs of special equipment for high-resolution and fine-shades-of-gray images and the massive data volume generated. The applications for interactive face-to-face consultations facilitated by VTCs, however, transcended many clinical disciplines. Although not originally designed for healthcare applications, VTCs were quickly integrated with medical peripherals such as electronic stethoscopes, endoscopic cameras, and other devices that provided additional diagnostic capabilities to telemedicine systems.

Telecommunication connections facilitate collaboration and partnership among distinct entities and foster the emergence of new forms of virtual organizations (33; JW Turner, unpublished data). These virtual organizations are no longer defined or limited by geographic boundaries or physical distance, but are facilitated through complex, high-speed telecommunication connections that allow "face-to-face" interaction and data exchange. As virtual organizations, integrated healthcare organizations can function effectively across distance and time.

Telemedicine faces different challenges depending on the needs of various sectors in healthcare. Patients demand that telemedicine improve the quality of care and access to specialists. Provider organizations such as hospitals demand that telemedicine be capable of reducing the cost of care. To some, telemedicine may offer opportunities to reduce operating costs by consolidating and streamlining management of multiple facilities. Physicians and other providers may see telemedicine as a means to improve their financial standing by attracting more

patients to their services. Others, however, may see telemedicine as a threat. The payers are concerned that indiscriminate use of telemedicine may increase the cost of care without improving outcomes. Many technological advances in medicine help diagnose, treat, and prevent certain illnesses, and their roles are generally well defined. However, the role of telemedicine is often unclear because it is composed of a network of individual devices and its role is in the operations and the process of care.

From these conflicting expectations and expanding technological advances, a new consensus is developing for effective telemedicine that can meet the competing needs.

## EXAMPLES OF TELEMEDICINE

Telemedicine applications are many, and the numbers are increasing rapidly around the globe. Here we highlight four different telemedicine applications: teleradiology as an example of remote diagnosis, telemedicine to manage spine surgery patients as an example of acute care, hemodialysis as an example of using VTC for chronically ill patients, and home care for diabetes as an example of low-cost home care. These examples are based on some of the telemedicine research projects in which the Imaging Science and Information Systems (ISIS) Center at Georgetown University Medical Center has been engaged over the past several years. We have applied telemedicine in radiology, kidney stone disease, pathology, surgery, dialysis, diabetes, treatment planning, and endoscopy, just to name a few. Through these projects we have developed a perspective that we are presenting in this review.

### Teleradiology

Teleradiology is the most mature telemedicine application and has evolved through multiple stages. In sharp contrast to VTC applications, teleradiology was developed through careful assessments and by establishing necessary standards and clinical requirements over a 10-year period. New industries have been formed by 1999, and virtual radiology service is now a reality. Teleradiology has been an integral part of picture archiving and communication systems (PACS), also known as image management and communication systems. PACS link all radiological-imaging systems to a network. The network distributes the images and other support data to radiologists over an electronic communication network. Figure 1 highlights the components of PACS and teleradiology. Several National Institutes of Health research grants initiated pilot PACS projects at several universities. Then in the late 1980s the US Department of Defense (DOD) initiated a major development effort for PACS and teleradiology (11). The Digital Imaging Network and Picture Archiving and Communication System project was a formal feasibility study that the DOD conducted in the 1990s at two demonstration sites, Georgetown University Medical Center in Washington, D.C., and University of

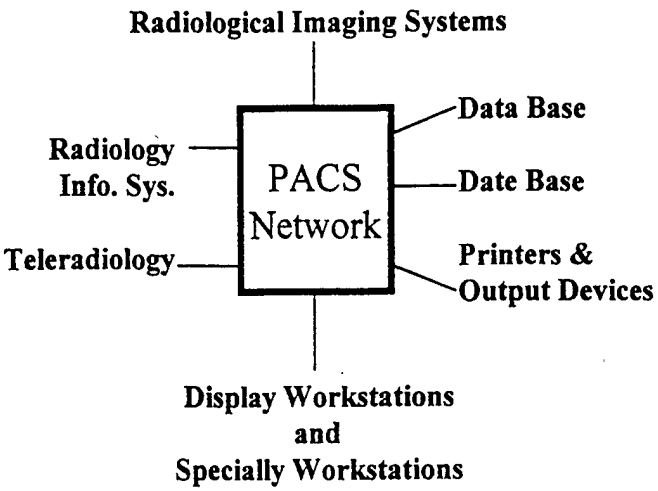


**FIGURE 1** PACS network.

Washington, Seattle. From the beginning, the DOD viewed PACS and teleradiology as a large-scale systems engineering project that needed to meet the requirements of the end users (21, 21a, 22). This requirement-driven engineering effort allowed the project team to identify key technological and management challenges in a systematic manner. The American College of Radiology and National Electrical Manufacturer Association, at the urging of the Food and Drug Administration, formed a working group to define digital interface standards for radiological-imaging devices. This effort evolved into the establishment of Digital Imaging and Communications in Medicine (DICOM) standards. All members of the radiology-imaging community have started supporting the DICOM standards and have implemented a strict policy for future technology development and deployment. All radiological-imaging components must maintain full compliance with these standards.

After the demonstration project, the DOD launched a new program, Medical Diagnostic Imaging System, to acquire and implement PACS and teleradiology systems for military medical facilities. Over a long 1-year period, ~30 experts, representing radiologists, information systems experts, engineers, scientists, managers, technologists, hospital administrators, and hospital planners, worked many weeks as a team to write comprehensive specifications for PACS. The Medical Diagnostic Imaging System technical-requirement document specifies hardware specifications, functionality, image quality, usability, database operations, network operations, and performance speeds. It also identifies the needs for new technologies in the areas of digital radiography and film printing systems and for faster communication, robust networks, efficient data storage and retrieval systems, integration with radiology and hospital information systems, and integration with teleradiology systems. The Medical Diagnostic Imaging System specifications became a de facto standard in understanding, describing, and developing PACS and teleradiology systems.

An example of a recent teleradiology program is a radiology network system that Georgetown University deployed for the US troops in Bosnia and Hungary

in 1996. Approximately 20,000 US troops were deployed to Bosnia-Herzegovina in December 1995, as part of the North Atlantic Treaty Organization peacekeeping force. A deployable radiology (DEPRAD) system was implemented to provide high-quality medical care and rapid and definitive responses to trauma and to minimize the recovery period before a patient's return to duty while minimizing soldier movement within the dangerous environment of Bosnia. The Imaging Science and Information Systems Center at Georgetown University Medical Center was requested by the US Army to design, develop, and implement a DEPRAD system that could support remote diagnosis of radiology images generated in the military medical treatment facilities in Bosnia and Hungary (18).

The teleradiology network linked three military facilities in Europe. Although the field hospital in Bosnia had an X-ray computerized tomography (CT) scanner, general radiography, ultrasound imager, and X-ray technologists, there was no radiologist. On the other hand, the field hospital in Hungary had a CT scanner, as well as multiple radiological-imaging systems, multiple X-ray technologists, and a radiologist. Figure 2 shows the DEPRAD network in Hungary. The Landstuhl Regional Medical Center in Germany is a comprehensive medical center and is the final stop in the European theater before a soldier is sent back to the continental United States. Additional equipment was required to establish teleradiology capability, which includes interface units, computed radiography systems, two types of workstations, film scanners, data storage and management

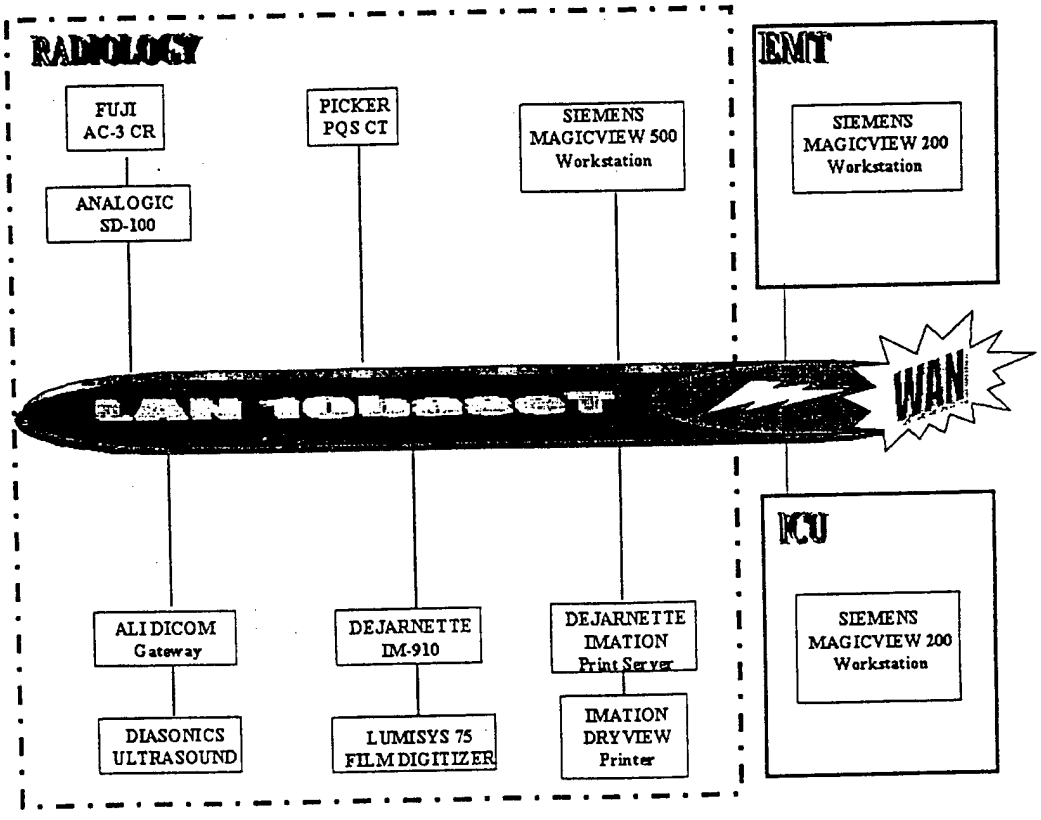


**FIGURE 2** Local radiology network in Hungary (very similar to Bosnia installation).

systems, and communication interfaces. These components were supplied to us from 10 different vendors.

To transmit images from Bosnia to Hungary, the data were sent via microwave from the field hospital to Tuzla Air Base, ~10 miles away, to uplink via a communications satellite to a satellite farm in Landstuhl, Germany, then through landlines to Hungary as shown in Figure 3. The transfer was ~1.54 mbps. Similarly, images needed to reach Germany were sent from the satellite farm in Landstuhl to the hospital over a landline. Communications between Hungary and Germany were based on a T-1 line. All sites did have access to the Internet so that, if required, information could be transferred via the Internet to other military facilities.

At both field hospitals, radiological-imaging services were conducted, using the mini-PACS on the local area network, without the use of films. Also, all images were read by radiologists either in Hungary or Germany.

We successfully completed systems integration, network testing, installation, and training at the three different sites in Europe within the 90-day deadline with only a handful of engineers and logistics staff. A number of difficulties occurred owing to conflicting interpretations (18) of yet emerging DICOM standards, but we were able to overcome these problems by the close cooperation of engineers from the participating companies.

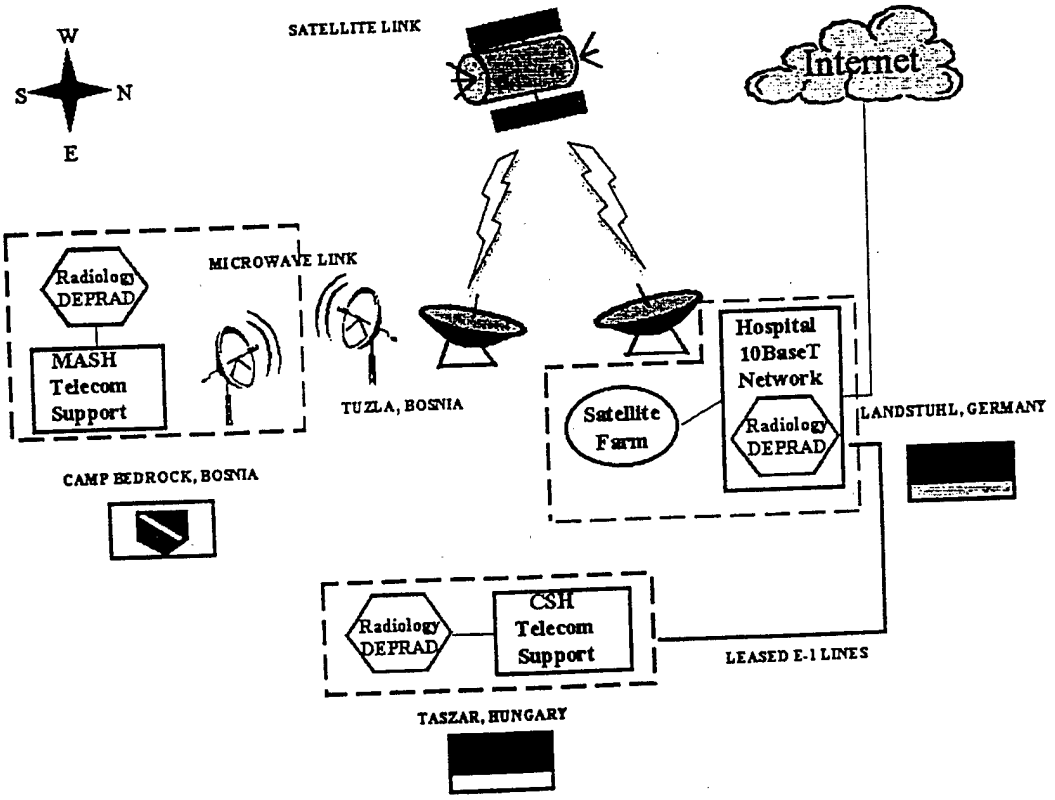


**FIGURE 3** Deployable radiology communication network connecting Hungary, Bosnia, and Germany.

DEPRAD and its experience clearly demonstrate that filmless radiology and remote diagnosis of radiology studies are viable alternatives in military global deployments. During the first 2 years of its operation, ~20,000 radiological cases were diagnosed with the teleradiology network. Teleradiology is seen as a standard of care in military medicine. Because radiologists are not deployed to mobile army surgical hospitals, DEPRAD will continue to provide radiological support in those situations.

The success of this complex project was made possible mainly by the focused development efforts by the medical imaging community and the government. DEPRAD is one of many key projects that generated confidence in the radiology community to deploy commercially developed telemedicine systems to reengineer existing radiology organization and to develop a virtual radiology service network covering the globe.

## Telemedicine for Neurosurgery Patient Management

Radiological images are one of the most frequently used diagnostic exams, especially for in-patients. In many telemedicine applications, video images are not sufficient and high-resolution radiological images must be made available along with other information. To facilitate such combined telemedicine applications, we worked with Viewsend Medical Systems to develop a telemedicine workstation with both teleradiology and videoconferencing capabilities. A pilot study was developed to assess the utility of such a system in managing perioperative neurosurgical cases between New York City and Washington, D.C. A separate telemedicine room was designated in New York, and a telemedicine workstation with a high-resolution film scanner was installed in the room. An ISDN service was installed to support 384 kbps between New York City and Washington, D.C.

In this pilot program, 10 patients were randomly selected from the neurosurgical in-patient service at the New York Presbyterian Hospital. Telemedicine consultation was then conducted by a New York surgeon, while he was at home in Washington, D.C., on weekends. Each patient underwent a complete neurological examination by a physician on site and also by a remote physician whose exam was assisted by a clinical nurse on site. Relevant radiological images were scanned into a telemedicine unit in New York and transmitted to a workstation in Washington, D.C. The remote physician conducted his examination via the workstations operating over the ISDN lines. Each examining physician completed a standardized data collection form that included a clinical assessment and both diagnostic- and therapeutic-management recommendations. Acceptance by the patients being examined was also assessed. After all patient evaluations had been completed, the responses of the two physician observers were compared and analyzed.

The correlation between the on-site physician and remote physician was perfect in half of the parameters evaluated, and in no parameter was agreement $<80\%$. Moreover, even for those patients for whom there were differences in

physical findings, the differences did not impact the overall assessment and management recommendations. Telemedicine performed well in the evaluation of surgical wounds. The telemedicine system used in this study not only reproduced subtle tissue colors accurately but also allowed for nonintrusive high-magnification viewing of the wound that is not routinely performed at the bedside. Despite a number of complex wound findings, none were misinterpreted.

The sensory examination was also more successful than we had foreseen. With the assistance of an on-site nurse and cooperating patients, fine details of sensation were readily assessed remotely. However, certain limitations in the telemedicine system for neurological evaluation became apparent. Minor technical difficulties in room configuration and camera tracking resulted in errors in gait assessment that otherwise would not likely have occurred. The motor exam, however, relies on the interpretation of an on-site assistant for gradations of strength that are less than full but greater than antigravity strength. Highly accurate assessments of strength could be carried out with sophisticated equipment but would be too cumbersome and are unlikely to affect decision making enough to justify the additional time and expense.

The telemedicine approach of managing patients for the application was technically satisfactory; however, it took much longer to complete the exam. Also, more time was required for the patients to be scheduled and brought to the telemedicine room by other staff members. Patients were satisfied because they were able to access the attending physician. Physicians were satisfied with their information and decision making capability from remote locations. In a large surgical group with multiple locations, it may be possible to justify the cost of this type of technology and the additional efforts required for its implementation.

## Telemedicine for Hemodialysis

One of the major difficulties in assessing the impact of telemedicine is in finding appropriate measurable parameters that can be directly linked to patient outcomes. The study of hemodialysis provided us with such a parameter for studying telemedicine's impact within that specific specialty. The mortality rate of dialysis patients can be directly linked to the dose of delivered dialysis. It is quite difficult to maintain a tight regimen of dialysis over a long period. The patients must be connected to a dialysis machine several hours a day, three or four times a week. Quite often they refuse to come to be dialyzed or disconnect themselves from the dialysis units earlier than prescribed. When these events happen, the possibility of complications and death can increase dramatically. Our goal is to reduce these medical complications by using telemedicine interventions.

Using a telemedicine network, we have been monitoring dialysis patients for over 1 year with a weekly "telemedicine visit" in addition to weekly physician visits, to maintain compliance with the dialysis schedule. Figure 4 shows the telemedicine network linking Georgetown University Medical Center, a dialysis center 10 miles away, and a physician's home, a few miles away. Transmission of images and data is achieved with T1 lines from the dialysis center to the

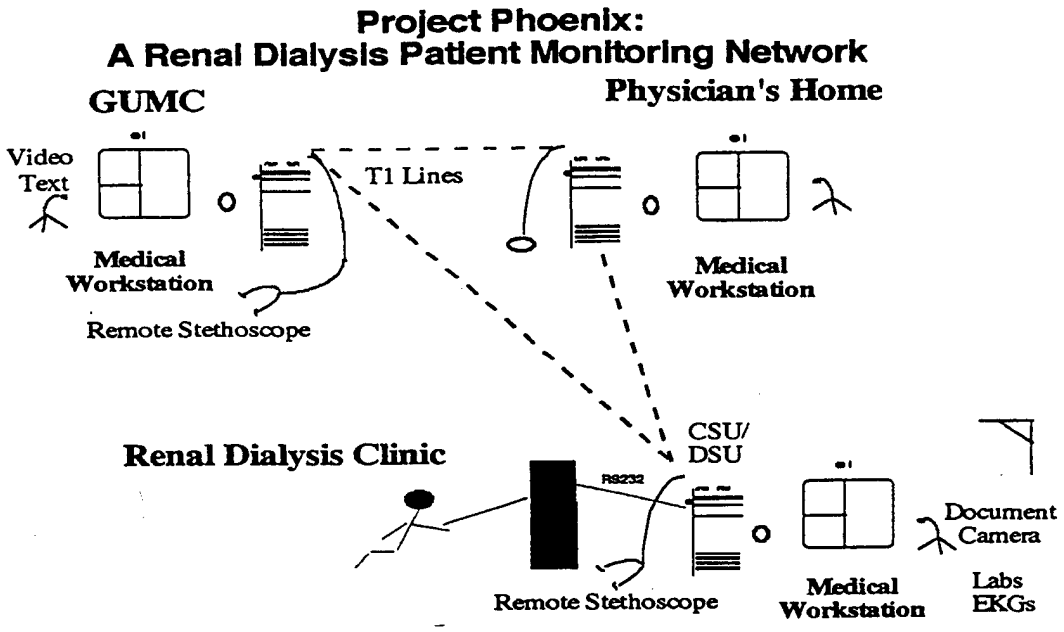


**FIGURE 4** A renal dialysis telemedicine network.

physician's office or home. The telemedicine session uses electronic patient folders containing relevant medical details, digitized X-rays, and lab values. We are able to achieve high-quality videoconferencing, capture still or video images, record remote stethoscope sounds, capture local or remote data (laboratory values and dialysis machine parameters), and modify the medical record.

The hemodialysis study compares two sites on the impact of telemedicine on patient outcomes. One site is the test site where telemedicine is used and the other is the control site where telemedicine is not used. For our assessment research we are measuring patient satisfaction, quality of life, cost, and security. Hemodialysis data (automated blood pressure, venous pressure, and arterial pressure; transmembrane pressure; blood flow rates; dialysate flow rates, conductivity, and temperature; ultrafiltration rates, and sodium delivery) are downloaded from the dialysis machines to a telemedicine work station. We have developed a website-based teaching program for patients regarding the security issues in our telemedicine protocol (http://www.imac.georgetown).

The formal data analysis is underway. Based on the initial 40 patients enrolled in each site and ~1500 individual patient contacts by telemedicine, we can see the trend. The use of telemedicine has become routine, and patient satisfaction (measured by interviews) has been high. Demographically the two sites differ in educational level (the telemedicine site has a lower educational level) and race (more African-Americans are treated at the telemedicine site). During times that the patient may wish to terminate dialysis early, or during emergencies, telemedicine, with its increased visual patient contact and interaction with the physician, is likely to help the patients maintain the amount of dialysis required. Physicians may be able to prevent some medical emergencies with adequate longitudinal

manage some of these conditions (such as imaging, laboratory reports, and prior dialysis parameters) is stored in various places throughout the medical center, not at the dialysis clinic. When emergencies or acute problems occur while the attending physician is off-site, it is now possible to provide real-time access to the patient or patient information needed to manage the situation. The physician can now intervene to provide immediate reassurance or encouragement to complete dialysis when the patients threaten to shorten their dialysis session. Additionally, a multimedia database for diagnostic audio, radiology images, and clinical still images stored in the patient folder versus conventional data management systems fosters an improvement in the monitoring of a patient's status over time.

Although it is too early to draw final conclusions, the impact of telemedicine in terms of improving the access, quality, and cost of care in this application would probably be modest. At Georgetown, physicians visit patients in person at each dialysis center at least once a week. In other services, physicians may visit patients once or twice a month. In those environments, telemedicine may have a more significant positive impact. Companies that manage dialysis centers around the country are very interested in exploring telemedicine capabilities, especially for dialysis centers in remote locations. Another area of growth may be home dialysis. Efforts are underway to determine how telemedicine can facilitate home dialysis.

## Home Telemedicine for Diabetes

Diabetes management may be another area in which the impact of telemedicine can be measured closely. Successful management of diabetes depends on maintaining blood glucose values within acceptable ranges. If telemedicine can help to maintain the sugar level, it can in turn improve the management of diabetes. Diabetes home-monitoring telemedicine enables the patient to better understand the disease and the physician to follow his/her patient's blood glucose level variations on a weekly basis to determine the patient's health condition and changes over time. This study has allowed us to remotely monitor patients who were previously diagnosed with type I diabetes, by using an electronic device to measure blood glucose levels and transmit these measurements electronically to the patients' physician in the Endocrinology Department of the Georgetown University Medical Center. Each patient is supplied with a One Touch Profile glucose meter (Johnson and Johnson) and an IBM-compatible personal computer with "in Touch" diabetes management software by Lifescan (Johnson and Johnson). The One Touch Profile meter is a diabetes tracking system that can store up to 250 readings and associate each reading with an event label to help both the patient and the physician analyze changes in the blood glucose level. To establish communications, the One Touch Profile has a data port that connects to a serial port of the computer. Each patient has a personal computer running Windows 95, and each computer has a 33.6-kbps modem. Data are transferred to the physician's computer via a standard telephone line. The user interface between the One Touch Profile meter and the database is the "in Touch" software, which consists of two parts: diabetes management and education systems.

After several patient training sessions, the diabetes management system enables the patient to transfer blood glucose readings from the meter to the computer, to analyze current and past data stored in the database, view and print reports that describe it, and set targets (high and low glucose levels). The patient can also see an average glucose level for a specified time frame and perform different file controls such as saving, importing/exporting, or archiving/restoring data. The system also allows the patient to analyze meter settings; retrieve, view, and reset the meter's option settings; and clear and delete readings stored in the meter's memory. The education portion teaches a diabetic patient or a member of his/her family. It also contains information on diabetes and diabetes management, and answers to frequently asked questions.

For this preliminary study we randomly selected 10 patients with type I diabetes (insulin-dependent patients) who are being treated at Georgetown University Medical Center and are all from the Washington, D.C., metropolitan area. Their ages vary from 13 to 65 years old. Each patient owns and uses a One-Touch Profile meter. It is a small device (~4.5 in. × 2.6 in. × 1 in.) that can be carried anywhere. The patient is supposed to test his/her blood three times a day (250 readings are automatically stored in the meter's memory). Once a week the patient connects the meter's data port to the serial port to be downloaded to the patient's computer. The computer is designed to run at a scheduled time each week and automatically initiates the dial-up and performs the connection to the physician's office, where a unique account has been created for each patient, and the database is updated. To retrieve a patient's data, the physician runs the "in Touch" software, chooses a patient from the list, and restores his/her data. This system allows the physician to view the latest data downloaded and identify patterns of glucose levels, select a specific reading, and view the associated comment from the patient if one exists. After reviewing the data the physician reestablishes an electronic communications link with the patient and sets personal diabetes targets and changes in insulin doses, exercise, or diet to optimize blood glucose level. Also the physician can answer any concerns or comments the patients may have sent along with their readings.

Our data show that, after enrollment in the program for 8 weeks, the average patients' glucose readings within range have increased from 34% to 51%. During this study none of the enrolled patients had a hypoglycemia or emergency room visit. Diabetes telemonitoring offers the possibility of eliminating distance and time as barriers to good blood glucose management, disease prevention, and, thus, a better quality of life and significant cost reductions in the short- and long-term hospitalizations, treatment, and emergency room visits.

For diabetes applications, there may be a motivation on both the physician's and payer's parts to promote telemedicine. First of all, the cost of the technology is minimal. Patients have glucometers that are paid for by payers, and some already have computers at home. In our case we purchased cheap used computers for this project. The concept of a health maintenance organization is based on the idea of keeping patients healthy and away from healthcare services. Telemedical monitoring of some chronic illnesses indicates that monitoring may help patients

stay healthy and reduce the frequency of medical events, thus reducing the cost of care over a long period.

## FRAMEWORK FOR UNDERSTANDING THE STAGES OF TELEMEDICINE DEVELOPMENT

Healthcare is a vast industry with many highly specialized activities. As such, one cannot expect a single telemedicine system to serve all applications. The role of telemedicine is particularly complex because it is a network of technologies to facilitate care and at times drive the changes in traditionally bound healthcare. Telemedicine must be seen as a large scale system engineering concept that deals with technology, organizations, financial considerations, and human needs. Thus, we suggest that the evolution of telemedicine occurs through a number of stages. The technology development process involves four basic stages: (*a*) the development of basic technological capabilities, (*b*) the development of relevant applications, (*c*) the integration and diffusion of technical applications within a complex environment, and (*d*) the transformation of the operating environment to incorporate the new innovations (Figure 5).

### Stage 1: Development of Basic Technological Capabilities

Telemedicine will require a new array of technologies in sensors, imaging, computer-controlled devices, communications, voice-driven systems, and intelligent database and network technologies.

With advances in digital compression technology, videoconferencing technology as a communication option is more feasible for healthcare institutions than it has been in the past because it allows for the use of existing telecommunications infrastructures (29). In addition, the video environment can mimic the traditional face-to-face environment, promising medical care at a distance "as if you are in the same room." As a result, telemedicine is making greater use of videoconferencing system technologies for teleconsultations between widely separated locations. These applications favor a synchronous connection between users, focused on acute rather than chronic conditions, and are characterized by connections between healthcare organizations. Because reimbursement by Health Care Financing Administration (HCFA) has been predicated on a face-to-face (in the same room) consultation, the focus on visual, synchronous media may be to satisfy HCFA's emphasis. Whereas video teleconsultations will continue to have their role in telemedicine, this technology could play a smaller role in the future as less expensive solutions become available.

During Stage 1 we see the development of new types of technology involved in various stages of the healthcare delivery process. These technologies may involve information capturing, information transmission, or interpretation. The Food and Drug Administration has identified on their website (http://www

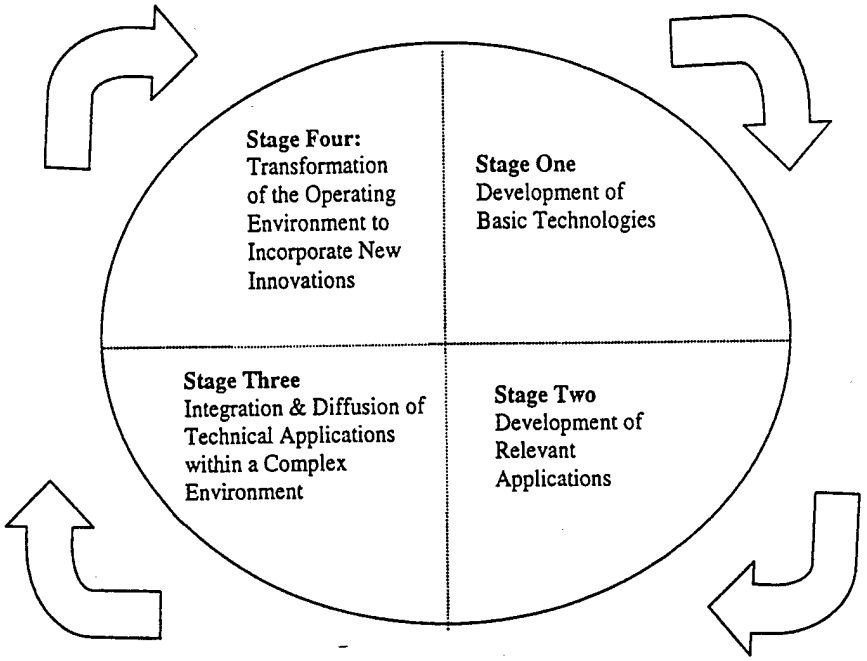


**FIGURE 5** Stages of telemedicine development.

.fda.gov) a list of new medical technologies that are needed and likely to develop within the next 10 years in the healthcare arena. This list is an excellent example of Stage 1 technologies.

## Stage 2: Development of Relevant Applications

In Stage 2, the acceptability of the technology for specific applications is validated and clinical efficacy is demonstrated. Many telemedicine efforts are directed toward questions of efficacy, cost effectiveness, and outcomes. The first telemedicine program review of US programs conducted by *Telemedicine Today* in 1993 revealed 12 active telemedicine programs, all using interactive video technology as a means of mediating doctor and patient interactions. The 4th annual telemedicine program review of US programs revealed a total of 80 telemedicine programs across 38 states, including Washington, D.C. (13). The majority of the programs incorporated interactive video systems applications, whereas a few used store-and-forward technology. During 1996 and the first four months of 1997, the survey found a total of 21,274 patient-clinician interactions taking place (these numbers excluded teleradiology and tele-home health applications) (13). According to Grigsby & Allen's (13) survey, the most common specialties using telemedicine as a means of providing care were mental health, emergency/triage, cardiology, dermatology, and surgery. This finding may suggest that these five specialties are more amenable to telemedicine applications than others. However, research conducted across 18 specialties within the Ohio State University telemedicine program suggested that telemedicine use may be more practitioner spe-

cific than specialty specific (20). Specialists who serve as opinion leaders within their healthcare organizations and are willing to be flexible and patient in adopting new communication technologies into their way of practicing medicine can make telemedicine applications work effectively in some capacity of their discipline.

The distinction between an asynchronous connection between users versus a synchronous connection between users is important. An asynchronous (or store-and-forward) connection allows the flexibility of dissolving time constraints, as well as physical boundaries, between users. Real-time connections are not necessary, allowing each individual participating in the interaction to fit the information exchange within his/her own time frame. Synchronous exchanges, on the other hand, can transcend geographic constraints but not time. In a synchronous connection, all of the sites involved must be connected at the same time. Synchronous connections can create prohibitive time constraints, especially when communicating across the country or internationally. In addition to the concerns associated with time constraints, bandwidth requirements for the connection can be higher, resulting in more costly connections.

Configurations for telemedicine networks have been multiple and varied. Perednia (24) designated that telemedicine locations be referred to as consulting sites (the site providing a specific expertise) and referring sites (the patient location requiring the expertise). In some situations, sites take on specific roles as either consulting sites or referring sites. In others, sites take on both roles. Each telemedicine network takes on its own unique configuration to answer the needs of the system.

In sharp contrast to teleradiology development, the broad category of telemedicine has been applied to a number of specialties, a number of technologies, and a variety of applications. As a result, the development of telemedicine technologies through the stages of the process is somewhat more complicated. For example, standards and clinical effectiveness for one specialty could be different from those for another specialty. Similarly, technical configurations that are required by one specialty might be different from those of other specialties. Therefore, conclusions and recommendations for use must be limited to the scope of the specialty and diagnoses involved.

Stage 2 describes the initial development of applications to meet the capabilities of new technologies. As these technologies begin to be used within various healthcare applications, practitioners can envision ways in which the innovation can be adopted on a grander scale. As more research and development are performed to support the use of specific telemedicine applications, greater support within specific medical disciplines and federal agencies will evolve.

## Stage 3: The Integration of Technical Applications Within a Complex Environment

Many telemedicine applications are realizing the third stage of the technology development process as concerns about reimbursement, licensure, credentialing, and standards continue to be debated at the national level. Our laws, credentialing

systems, and reimbursement mechanisms are not created with a virtual and distributed environment in mind. These systems and mechanisms are based in traditional conceptions of centralized physical place. Physicians are currently licensed in the state where they practice. Consultations occur with the physician and patient in the same physical space. When these laws and systems were created, a synchronous consultation between a patient, the patient's primary care physician, and a specialist 50 miles away, occurring in the same room, was impossible.

In an extended environment, where the patient and physician are located in different physical environments but connected via a telecommunications link, where does the consultation happen? When an interaction occurs between a primary care physician in one state and a specialist in another, where does that consultation happen? Instead of recognizing the uniqueness offered by telemedicine, our licensing, credentialing, and reimbursement systems have tended to ignore this new extended environment. Efficiencies and economies gained by using a physician from a remote location are lost, because licensure and credentialing systems now force these individuals to align themselves with the physical space of the patient. Healthcare organizations are beginning to recognize the transformation necessary to incorporate radical new ways of providing medical care into their current methods of doing business. The adoption and diffusion of these potentially revolutionary technological advancements bring with them additional human resource capabilities for organizing, scheduling, and coordinating telemedicine efforts (1, 31, 33, 34).

The adoption and implementation of medical technology within healthcare organizations are complicated processes. The dual-authority system within healthcare organizations creates opportunities for potential conflicts in telemedicine-related decisions. The juxtaposition of two main groups, administration and medical staff, within the same organization requires acceptance and adoption by both groups for implementation efforts to be successful (5). Although many decisions within the healthcare organization concern areas that are clearly demarcated as belonging to one group's authority or another's, telemedicine applications fall into a common area where both the medical staff and the administration have valid interests. Telemedicine applications offer the opportunity to develop efficient connections between healthcare organizations, which facilitates the creation of integrated delivery systems. However, telemedicine also increases the competition for patient care dollars, thus some clinical practioners may see it as a threat.

Telecommunications innovations themselves are also distinct from many other types of innovations within a healthcare organization. The dynamic and changing nature of the telecommunications industry requires new visions for adoption and management. As Keen (17) suggested, when telecommunications was primarily a telephone utility, cost and service were the main issues. However, with the capability and opportunities created by the merging of telecommunications and computer technology, the business case for the adoption of telecommunications

innovations requires organizational vision and policy development. A short-term decision based on the bottom-line costs associated with the building of a telemedicine system does not take into account the long-term benefits of establishing relationships among distinct organizations. Similarly, short-term approaches may ignore the gradual adoption and implementation processes associated with the transformation of clinical care to accommodate this new technology. The primary barriers to program sustainability noted by Grigsby & Allen's (13) survey respondents were reimbursement concerns and the high cost of telecommunications. Although, these barriers represent challenges to the diffusion of telemedicine, several other barriers provide additional challenges. Sanders & Bashshur (27) identified six problem areas facing the development of telemedicine applications: (*a*) interstate licensing and institutional credentialing of physicians, (*b*) legal liability and litigation, (*c*) individual client or patient autonomy and the right to privacy, (*d*) reimbursement, (*e*) knowledge about telemedicine, and (*f*) system design and infrastructure. As data continue to move to digital form, questions of patient confidentiality and information privacy are triggered by telemedicine solutions (10). In addition, organizational and individual barriers influence the ability of healthcare practitioners and their management structures to adopt a new method of delivering care (33). These barriers, although accurate, are symptoms of a larger barrier—the cumulative transformation and translation of what healthcare delivery means in our traditional environment to what healthcare delivery means within a virtual environment.

## Stage 4: The Transformation of the Operating Environment

Stage 4 describes the transformation of the environment to take advantage of telemedicine capabilities. An example of this transformation can be seen in teleradiology.

As mentioned earlier, the radiology community is ahead of the rest of the telemedicine industry in perfecting the technology of teleradiology and its integration into the existing healthcare system. Establishment of standards and advances in computer technology in general have eventually brought down the cost of teleradiology systems. Teleradiology also created dramatic changes in the traditional way diagnoses are made using films hung over a lighting system. After a great deal of debate and research, moving the images over a network and reading the images on electronic displays have been well accepted. Questions of image quality caused by data compression were gradually resolved as more radiologists gained experience with data compression technology. After the question of image quality was resolved, the interest shifted to the needs for higher performance technologies with higher productivity. These technologies will then be integrated with enterprise-wide information systems for higher efficiency.

One important factor in making teleradiology economically feasible is that diagnosis made on a teleradiology network is reimbursed by Medicare, Medicaid, and other payers of healthcare. Proven and standardized technology and the ability

to get reimbursed for services have created a favorable environment for teleradiology to expand.

In the US military, teleradiology is the standard of care. The most advanced radiological imaging systems, like X-ray computerized tomography, can be installed in the field hospitals for critical care with the images being read by radiologists anywhere in the world. A new industry of radiology service based entirely on teleradiology has been formed. Images generated at any radiological imaging facilities can be transmitted around the world for expert diagnosis. A radiology service in Virginia can receive MR images from a number of MRI centers in the US, Canada, and Great Britain for expert diagnosis. Often teleradiology is used as a strategic and competitive advantage in certain healthcare markets where radiology groups are competing for limited healthcare dollars. The radiology community has transformed itself by taking advantage of the capabilities of teleradiology technology.

With telemedicine's growth and expansion, the needs of specific medical conditions and populations have generated some changes in the telemedicine's future growth potential. We discuss two shifts in telemedicine applications: (*a*) changes in the use of synchronous, interactive video connections as the primary telemedicine technology and (*b*) changes in the settings where telemedicine takes place. Perednia & Grigsby (26) argued that healthcare must be technology neutral. They suggested that the diagnosis and management of any clinical condition require that a healthcare provider interpret the information. The amount of information requisite to diagnosing a patient varies depending on the complexity of the condition. Therefore, the healthcare condition should determine the mediated form of the consultation's discourse. That mediated form can take place in a traditional, face-to-face, in-the-same-room consultation, a telephone consultation, a store-and-forward consultation, or an interactive video consultation. The complexity of the information required should determine the medium through which the information is transmitted (26).

As technologies become integrated within specific applications, new technologies develop that can improve the efficiencies and quality of the existing system. At this point the cycle begins again. In some cases, the telemedicine innovations will evolve within an existing healthcare delivery environment. In other cases, telemedicine innovations will expand the environment to new locations. An example of this expansion can be seen in the use of telemedicine within the home.

## EMERGING ENVIRONMENTS

Many telemedicine research projects until now focused on the use of video teleconferencing systems to manage acute care cases, such as trauma care surgical follow-ups and other emergency cases. Current research suggests that the use of telemedicine capabilities to manage chronically ill patients may become clinically relevant and economically cost effective.

More than 90 million Americans live with chronic illnesses such as diabetes, hypertension, asthma, and renal failure. Chronic diseases account for 70% of all deaths in the United States, and medical care cost for the chronic illnesses now accounts for more than 60% of the nation's medical cost. The illnesses account for one third of the years of potential life lost before 65. The cost to the society by acute conditions such as cancer, injuries, and others is not insignificant, but the management of chronic illness comprises the most costly activities in US healthcare. This cost is increasing steadily owing to the increase in the older population. Furthermore, a greater percentage of the older population is living much longer than before.

The patient care protocol for chronically ill patients is well established. If patients are managed properly, they can lead very satisfying and productive lives. If the illness is poorly managed, the illness can lead to complications and hospitalizations that will increase the healthcare cost dramatically. Often the ideal management of chronic illness calls for patient compliance with self-testing, healthier life styles, healthier diets, and timed medications. These activities generally take place in patient homes, thus home care is becoming an important site in healthcare (12).

Telemedicine systems installed in the home can assist the patient to follow the illness management routines established by the physician (6). These systems can facilitate self-testing and self-analysis. The number of diagnostic tests a patient can do at home is increasing and the results of these tests can be communicated to appropriate physicians using the telemedicine network. These systems can also help patients to follow medication instructions and other self-help instructions. The system can be used to communicate with the physicians and to obtain helpful educational information from the Internet.

As more technology is placed in the patients' hand, the patients will have greater access to information and can assume greater risk on their own. It is difficult to predict how this new home healthcare technology trend will change the way we provide healthcare in the future. However, it is clear that these changes will take place fueled by emerging telemedicine technologies.

Many smaller hospitals are being merged with larger hospital chains, and telemedicine networks of some sort will play a significant role in reshaping the healthcare industry. As the consolidation takes place, economies of scale will cause consolidation and streamlining of operations. In the past, there may have been several competing hospitals in a city that offered "full service" care in all specialty areas. Now that service can be consolidated into a single physical location with telemedicine links to other facilities. In a large healthcare enterprise, the government's willingness to reimburse for telemedicine may not be as important if telemedicine can improve the efficiency and reduce the overall cost of care.

The pattern of healthcare in the past was physician-centered and hospital-centered. In the future it may become more patient-centered. Telemedicine applications, as an integral part of the accelerating technology revolution, will have a profound impact in the transition.

## CONCLUSION

As shown by our discussion of the cases, as well as our description of the stages of telemedicine development, telemedicine applications are growing through the development of new technologies, realization of new applications, and the slow integration of these technologies into the current practice of medicine. The broad field of telemedicine has much to offer in the way of solutions to specific problems, as well as in expanding our understanding and conceptualizations of space and time regarding where healthcare takes place. As we continue to learn from the developing technologies and emerging applications, it is important for us to recognize the process of change and the opportunities that come from this process. Telemedicine offers the opportunity for members of the healthcare industry (patients, practitioners, researchers, regulators, teachers, policy makers, etc) to re-examine the current way that medical care is practiced. From this examination, learning, transformation, and new practices can emerge.

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# Chapter 5

# Systems Integration for PACS

## 1.0 Introduction

When one talks about an integrated Radiology Department, one must consider the established and planned information systems in and the workflow of the department. It is not enough to look at the data flow throughout the department; one must also look at Radiology from the process perspective.

The first part of this chapter (Sect. 2.0) deals with data flow and how information is shared between Radiology or Hospital Information Systems (RIS or HIS), Picture Archiving and Communications Systems (PACS), and imaging modalities. Ownership of information, options for connectivity, testing connectivity solutions, and administration of the PACS are discussed here. The information provided in Sect. 2.0 will provide one with an understanding of the complexities, options, and areas of concern for connecting multiple information systems within a Radiology department.

The second part of this chapter (Sect. 8.0) deals with the processes within the radiology department. It provides solutions to support the entire radiology workflow. Access to digital information does not necessarily translate into a better organized, more efficient, or improved service department. The integration of systems for the exchange of data has to be complemented by the integration and automation of processes. This part of the chapter deals with the workflow perspective of system integration.

Since processes in film-based radiology departments can be inefficient, labor-intensive, costly, and time-consuming, one must look to change these processes when moving from a film-based to a digital department. Sect. 8.0 looks at Information Systems that help manage these changes

## 2.0 Approaching integrated systems: what the user needs to know

In this section, the authors hope to convey the importance of multiple systems sharing information. Standalone information systems require multiple data entry by a single person, the use of different user interfaces, and redundancy of stored information. Connectivity between these systems can reduce or eliminate errors caused by redundant data entry, errors in data entry, and unsynchronized databases.[1] Over the years, vendors have moved closer to providing integrated solutions, however, there is still far to go. In order to understand fully the problems, we need to start by understanding the types of data that each side has ownership of and the data required by the other systems

### 2.1 Domain boundaries

When one thinks of integrated information systems within a hospital environment, one can only dream about the time when all types of data are accessible from a single application. Until that time, each system, registration, ancillary departmental, scheduling, and digital imaging networks must be addressed individually as well as in a connected environment. Focusing on the relationships between the RIS, HIS, PACS, and the modalities within a Radiology department produces a complicated web of who owns what data and where are data boundaries drawn. There are certain pieces of data needed by all the systems, like patient demographics. Finding a mechanism to enter data into all the systems seamlessly and without the burden of duplicate data entry is the key to successful network integration. The best way to approach this problem is to define which systems need to control which data.

### 2.2 PACS domain

Different information systems throughout a medical center generate much of the information that is used throughout Radiology. When discussing a connected environment, it is important to understand which system maintains ownership or control over which pieces of information. The role of a PACS is to maintain the digital images acquired within the Radiology Department. Therefore, the PACS should control information that is directly related to the acquired study. This includes the images themselves along with information relating to how the image was acquired (General Image Module Attributes DICOM 3.0

standard part 3, Table C.7-7)[2], the equipment used in the acquisition, and general information about the image pixels. In addition, data items that the PACS needs to have control over relates to the specific exam type (CT, CR, etc.). Similarly, information related to the display and printing of the image would be property of the PACS. The PACS may also behave like a film tracking system and track the digital exam/study/image by location. A RIS may require access to this information. Then through an interface or a direct integration between the two systems the data would be available.

### 2.3 RIS/HIS domain

The RIS/HIS should be in charge of patient registration activities, which result in demographics and exam information including scheduling. A RIS/HIS will track the completion status of exams resulting in a radiological report or transcription data. The RIS/HIS should be responsible for disseminating the results of the exam to the PACS if required. The RIS controls the transcription of the report , although this should not preclude the PACS from creating, modifying, or allowing electronic signature of a report. A well-implemented interface or true integration would allow for these functions. An institution that maintains a separate RIS and HIS will need to have an interface/integration between those two systems for the sharing of the demographics, exam, and scheduling information.

### 2.3 Shared domain

In the world of separate information systems and interfaces, not true integration, it is important to understand which system is responsible for which data. This does not preclude one system from accessing another system's data and it guarantees accurate information in your database. Therefore, it is difficult, to assign coownership of data to two distinct systems. One of the systems must be responsible for the data and therefore considered the controller of the information. The sharing of data and the ability to modify the data by multiple systems is a necessary result of an interface or integration. However, if a discrepancy does exist, one system is considered truth and the other must change to synchronize with it.

## 3.0 Modalities, where do they fit?

Today's imaging modalities are not configured to connect to a RIS or HIS and therefore require duplicate data entry to start an exam. This often requires entering patient name, ID, DOB, gender, and other pieces of data that currently exist in the RIS/HIS. In the pre-PACS world of Radiology this did not lead to many problems since paper charts were matched to hard copy films. However, in the PACS environment, duplicate entry of patient demographics into the modality console becomes a major concern. Incorrect or missing patient information or study ID numbers can cause a study to be linked to the wrong patient or incorrect order thereby leaving the study unreported and a diagnosis unavailable.[3]

Early days of PACS tried to get around this problem by using profiling of exams to match them to the orders based on name, DOB, date and time of study, and ID number when available. Profiling did not work well since many modalities do not capture unique exam/study IDs making profiling less effective. The DICOM Service Class, Modality Worklist Management, allows patient and study information from the RIS/HIS or PACS to pass to the modality and present a pick-list to the user. The user then selects the study from the picklist and the newly acquired images are attached to the study. Many installed modalities do not have Modality Worklist Management capability, so a separate interface computer is required that interfaces the console and/or the central computer of the modality, to the PACS or RIS/HIS.

## 4.0 Examples of connectivity in a digital radiology environment

One common example of the benefit of interfacing PACS and RIS/HIS is for the restoring of archived exams. In an ideal film based world, when a patient comes into the Radiology department for a study, a film librarian pulls their previous related exams from the film library and makes them available as a comparison study. In reality, many of those previous and archived exams are not available. This is one of the most compelling reasons for using a PACS. In the digital world, performing a new study should trigger a restore of the patient's previous digital exams from the archive. The new and old studies will be available on local storage for the Radiologist as he/she begins the primary review process.[4]

An interface between a RIS/HIS and a PACS can facilitate this process. As exams are scheduled and progress from scheduled through complete, this information passes to the PACS. Then, based on predefined criteria, restoration of previous exams from the archive to local storage occurs. This provides for all information at the fingertips of the radiologist when he/she needs it. Without connectivity between the PACS and RIS/HIS, the retrieving of these studies from the archive would not occur until the time of primary diagnosis, and it would be a manual process. Thus, if retrieval times from the archive were long, the potential to ignore previous studies would increase.

Another benefit of an interface is seen on systems that have distributed local storage. Some PACS workstations store exams locally on the workstation's hard disk. An interface between a RIS/HIS and PACS can facilitate the transfer of new and old studies for a patient to the local workstation automatically based on predefined criteria.[5] This process of autorouting is used to pre-load a workstation for a radiologist or clinician. Without autorouting of studies to the proper workstations, a Radiologist or Clinician may ignore studies rather than request them from the long-term storage and wait for their transfer to the workstation. In the film-based world, a film librarian often pre-loads the alternators with the new and old studies of patients. Then everything is available for the radiologists when they sit down to review their cases.

The transferring of reports between a RIS/HIS and PACS can be automated based on predefined trigger events or based on process models as defined in the second part of this chapter. Thus, having all information available to the radiologist is a benefit of an interface.

## 5.0 Options for connectivity

There are different options for sharing information between a PACS, RIS/HIS, and imaging modalities.[6] All of these options have a trade-off between ease of development, functionality, and cost. As might be expected, the higher the cost to develop the interface, the more difficult it is to develop and implement but the more functionality it provides. This does not mean that the more basic options do not offer a benefit, just that one must be sure to understand the differences and decide on the option that is best for their situation.

## 5.1 Multiple simultaneous applications

One way to provide access to all information from multiple systems simultaneously is to allow multiple applications to run off a single workstation. In the increasing world of PC based workstations, it is common to run multiple applications from a single PC. This allows a user to view information on the RIS or HIS application while running the PACS application. This allows one to view reports and other information while looking at the images for a single patient. While this is the simplest type of "interface", it does have its problems. First, the inadvertent viewing of two different patients at the same time is high leading to potential problems with a diagnosis. Second, each application may use many computer resources like memory and can cause technical problems on the workstation. Third, some vendors may not allow other vendors' applications to run on their workstation. They may fear it would violate the FDA regulations, especially if some new software has to be loaded on the PC to make this work.

Thirty different companies and groups have formed a working group to investigate and develop a standard that allows for the visual integration of healthcare technology. This standard is known as CCOW, Clinical Context Object Workgroup, and it specifies the capability for multiple applications to "coordinate" on the same patient no matter which application was used to select the patient.[7] CCOW allows one application to select a patient and then subsequent applications that are opened, that follow the CCOW standard, automatically go to the same patient record. This type of technology limits the problems of selecting or viewing different patients at the same time and reduces or eliminates the need for duplicate entry of patient information to select a patient's record.

## 5.2 Unidirectional interface

With a unidirectional or one-way interface data flows in one direction only from RIS/HIS to PACS or PACS to RIS/HIS. Acknowledgement of receipt of data may pass back from the receiving side to the sending side, but no new clinical information would pass back. Normally with a one-way interface, the RIS/HIS is the primary system passing data to the PACS. This relates directly to the earlier discussion in this chapter regarding domain and ownership of data. The sending side makes corrections or additions to the data and transfers the changes to the receiving end. This is a quick and inexpensive way to build an interface

between two systems. However, the limitations of this type of interface make it less than ideal.

With a one-way interface a user is still required to use both systems to get at everything they need. This means that they must have access to both systems and they must be trained and comfortable using both systems. If a user on the receiving system notices data entry errors, he/she must stop what he/she is doing, go to another application, usually on a separate workstation, and make the changes. More than likely, the user will elect to make the changes later, perhaps forget to make the change, and the data remains unchanged. This leads to inconsistencies in the two systems' databases and can lead to unidentified studies, improper diagnosis, and even lost information.

### 5.3 Bi-directional interface

A bi-directional or two-way interface implies data flowing from the RIS/HIS to the PACS and from the PACS to the RIS/HIS. There are still two databases, one for the PACS and one for the RIS or HIS, but the stored data can flow between the applications. The data that flows between the applications may be stored in each database, or merely used by the application and then discarded, if the system with domain over the data maintains it.

It is possible with a bi-directional interface to have limited two-way data transfer between the systems, and even unequal data flow. That is, some bi-directional interfaces allow data elements to pass from one system to the other, but not have all the data passed back. A good example would be the radiology reports and their status. Reports transcribed into the RIS pass to the PACS before their status changes to approve. A limited bi-directional interface may allow for changes in the patient demographic information on the PACS but not the report. The PACS sends the resulting demographics changes back to the RIS, but any changes to the report would need to occur on the RIS. Similarly, maybe the PACS can edit the report and pass the modified report back to the RIS, but it does not allow for electronic signature on the PACS. In this limited type of bi-directional interface, the user would still be required to use both the RIS and the PACS to complete the task of reviewing, modifying, and signing reports.

A true bi-directional interface that allows all necessary information to pass between the systems provides the user with access to everything in a single place. However, bi-directional interfaces are difficult and costly to develop. Vendors don't like other applications changing information for which they have ownership.

### 5.4 Integration

The integration of a PACS and RIS/HIS is to make the systems appear as one while they may still be two separate systems. With true integration applications appear to share a single database and ideally a common user interface. There are at least two ways to accomplish integration. First, the RIS/HIS and PACS can be one large system, where the images and PACS functionality are data objects of a RIS/HIS.[8] While some RIS/HIS vendors are looking into this approach and beginning to investigate and even offer access to digital images from within their RIS/HIS product lines, this is not available today. The more likely approach will be for each system to be able to query each other's database and have access to the information stored in each other's database. Utilizing standards like HL-7, SQL, CORBAMed, CCOW, and DICOM, vendors of PACS and RIS/HIS would allow for the passing of information between the systems and the modifications to the data in each other's database.

A clinical data repository can provide a mechanism for access to all patient information in a single location.[9] The BJC Health System and Washington University School of Medicine have developed and implemented a large integrated clinical information system. Using standards like HL-7 and DICOM they have developed a data repository containing patient demographics, radiology, cardiology, pathology, and medical records transcription reports, clinical labs and microbiology results, vital signs, and radiology images. Thus, this type of system allows access to all the necessary information from a single workstation while allowing the individual departments autonomy in selecting the clinical system of their choice.

## 6.0 Testing the connectivity options

Upon completion of a connectivity implementation, a plan for testing the connectivity must be in place. A test plan specifies all possible scenarios that one expects to encounter while operating the PACS in the

connected environment.[10] The test plan should also include scenarios that one does not expect to encounter but might see do to user error, or unexpected results. This plan should test limits of data that can pass between the systems. It should check for missing values, incorrect names with valid ID's, and other errors that are likely to occur. If automatic restoring of data from the archive is a result of your interface, than that needs thorough testing. Testing of all configuration options and user definable options affected by the connectivity strategy is necessary.[11]

Detailing the requirements for passing and failing the test plan and documenting the results is critical. The document will provide recourse if the connectivity strategy does not perform as was expected. Identify individuals responsible for each test so that the responsible parties can address each issue if problems arise.

The speeds of transactions and transaction triggers are another area of the connectivity solution that requires testing. Transaction triggers relate to the function on one system that causes a transfer of information to another system. For example, the scheduling of a patient for a follow-up chest x-ray on the RIS/HIS Scheduling system would trigger a transaction sent to the PACS to restore the patients previous Chest X-ray from the long-term archive. The test plan specifies how to verify that the trigger is successful and how long these types of transaction requests should take. Testing of all transaction triggers and verifying that they operate as expected, even when tested at their limits, is critical to acceptance of the connectivity solution.

Lastly, when developing a test plan, do not ignore the error conditions, how the system responds and how it reports messages to the user. Here you want to ensure that if a problem exists, the software notifies the user and logs the problem.

All of these conditions should be included in a comprehensive test plan for the connectivity solution. There needs to be a mechanism in place for accepting or rejecting the solution before using it clinically.

## 7.0 Administration of the PACS

The decision to purchase a PACS is a decision made from within the radiology department. Input from outside departments like hospital administration is important. However, compliance from within the

radiology department is critical to the success of any PACS project, and thus the decision to purchase a system should come from within radiology. Once a decision to go filmless is made, the process of selecting, installing, and implementing a PACS, needs to be a shared responsibility between the radiology department, hospital administration, and the hospital information systems group. When the system is in place and prepared to "go-live", customization of configuration data needs to occur. To determine which department is responsible for configuring, implementing, and the follow-on maintenance and support of the system can be a difficult decision.

### 7.1 Argument for the radiology department

Radiology departments are the primary users of the PACS and therefore often feel the need to maintain firm control over the system. Often the department, to be responsible for the day-to-day operations of the system, hires a systems administrator. The tasks they are responsible for includes creating new user accounts, fixing studies that were acquired improperly, dealing with user problems, and checking logs. In hiring a system administrator, x-ray technologists with an interest in and knowledge of computerized systems become likely candidates. It is important that the administrator understand the workings of a radiology department as well as the intricacies of the PACS. Retrained technologists make good administrators for many reasons. They can help improve compliance with using the PACS, train the users, and provide assistance to them. They are also used to handling patient confidential data and understand the data , which can aid in the cleaning up of problem records in the database.

However, a PACS is a large complex computer system that needs dedicated attention to hardware and software concerns and upgrades, proper handling of the archive and user accounts, patient confidentiality, and security concerns. Therefore, it is necessary to have an individual involved in the maintenance and support of the PACS that understands the network environment which the PACS operates in, the hardware that is used in the development of the PACS, and the software applications and languages that the system is built upon.

## 7.2 Argument for hospital/institution information systems group

Because of the previous paragraph, it is often assumed that the Institutional IS departments should be responsible for the PACS. Institutional IS departments staff their departments 24 hours a day 7 days a week. They are accustomed to dealing with long-term archiving issues, back-up concerns and other common IS tasks. A PACS is about managing data pure and simple. It is data just like any other clinical data. Just because the data is images does not mean it requires different handling than text based data. These are functions that the Institutional IS groups are used to handling.

Since the IS group is responsible for most of the other clinical information systems, they can be extremely helpful in the development and implementation of an interface between the PACS and the other information systems like radiology and hospital. They should be used to training users, and configuring new systems. The IS department is an often overlooked resource when a PACS is implemented.

## 7.3 Arguement for joint administration

IS personnel often lack the clinical background or knowledge to implement a PACS in a department. While it is a computerized information system, it is still an extremely specific clinical application that requires special handling. Therefore, the ideal implementation would include the IS department handling the technical aspects while receiving clinical support and guidance from the radiology department. A designated radiology staff member can ensure the clinical usefulness of the system while the IS staff ensures the technological usefulness.

The role of the departmental staff person is to ensure that the system configuration and setup allows clinical users access to the information that they require. Radiologists need to review studies and mark them as reviewed while referring physicians only require access to their patient's studies for clinical review. They do not need to mark studies as read. Technologists require the ability to log exams as started, completed, and to make changes to the orders to reflect exactly what transpired. They may also require the ability to modify patient demographics and order entry data, merge patient records and update exam status as necessary. These are the types of decisions a radiology

personnel can make that the IS staff person would probably have no knowledge of.

On the other hand, IS personnel are used to handling 24 hour, 7 day a week requests for broken hardware, user access problems, and reloading of exams that are off-line. They normally staff the computer room 24 hours and have on-call personnel that can handle the technological problems that might arise after hours.

While there is room for the department and IS support of the PACS, it is critical to understand that these individuals/groups must work together to ensure a successful PACS implementation. These groups are not at odds, but have one common goal. That goal is to guarantee the clinical as well as technological usefulness of a highly specialized computerized information system. The key point to remember is that it is nothing more than an information system whose primary data is a large file of bits and bytes that represent a radiology image.

## 8.0 Automation and systems integration

In the first part of this chapter we have looked at systems integration from the *information* point of view, and we have discussed the necessity to share data among the various sub-systems. We have already mentioned the needs to automatically transport information, autoroute, or pre-load data. *Data flow* is certainly an important aspect of system integration, but by far not the only one. We now have a look at radiology from the *process* perspective, and we discuss solutions to support the entire radiology *workflow*.

### 8.1 Terms and acronyms

Some of the essential terms used in this chapter are defined as follows:

***Activity:*** A description of a piece of work that forms one logical step within a *Process*. An *activity* may be a manual activity, which does not support computer automation, or a workflow (automated) activity. A workflow activity requires human and/or machine resources(s) to support *process* execution; where human resource is required an activity is allocated to a *Workflow Participant*.

***Application System:*** A general term for a software program that interacts with a *Workflow Enactment Service*, handling part of the processing required to support particular *activities*. Examples: RIS, PACS, modality

***Business Process Re-Engineering:*** The process of (re)-assessment, analysis, modelling, definition and subsequent operational implementation of the core business processes of an organisation or other business entity

***Process:*** A co-ordinated set of *activities* that are connected in order to achieve a common goal.

***Process Model:*** A formalised view of a process, represented as a co-ordinated (parallel and/or serial) set of *activities* that are connected in order to achieve a common goal.

***Organisational Model:*** A model which represents organisational entities and their relationships; it may also incorporate a variety of attributes associated with the entities. Most workflow management systems maintain such information as part of their *Workflow Control Data.*

***Process Instance:*** The representation of a single enactment of a *process.*

***Workflow or (workflow management):*** The automation of a business process, in whole or part, during which documents, information or tasks are passed from one participant to another for action, according to a set of procedural rules.

***Workflow Enactment Service:*** A software service that may consist of one or more workflow engines in order to create, manage and execute particular workflow instances. Applications may interface to this service via the *Workflow Application Programming Interface* (part of WAPI).

***Workflow Engine:*** A software service or "engine" that provides the run time execution environment for a *Process Instance*.

***Workflow Management System:*** A system that defines, creates and manages the execution of workflows through the use of software, running on one or more workflow engines, which is able to interpret the *Process Definition*, interact with *Workflow Participant*s and, where required, invoke the use of IT tools and applications.

***Workflow Participant:*** A resource which performs the work represented by an *activity*. This work is normally manifested as one or more *Work Items* assigned to the *Workflow Participant* via the *Work List*.

***Work Item:*** The representation of the work to be processed (by a *Workflow Participant*) in the context of an *Activity* Instance within a *Process Instance*.

***Work List:*** A list of *Work Items* associated with a given W*orkflow Participant* (or in some cases with a group of *Workflow Participants* who may share a common *Work List*). The *Work List* forms part of the interface between a *Workflow Engine* and the *Work List Handler*

***Work List Handler*:** The interface between a *workflow enactment service* and a *workflow-enabled application system*.

## 8.2 Processes in radiology: How many people and systems are needed to support the work of the radiologist?

Processes in film-based radiology departments can be very inefficient, labour-intensive, costly and time-consuming. On average, 5 to 6 members of supporting staff support one radiologist in a conventional department. This does not only generate costs, but the large number of administrative manual process steps tends to result in inefficient and slow operation. One of the key radiological performance parameters, for instance, the time needed from image production to result delivery to the referral source, can easily be 24 hours or more in a film-based department.

This will be quite unacceptable in the future. In a situation of shrinking health care budgets, increasing cost pressure and growing demands to increase the efficiency and the quality of radiological services or health care enterprises are forced to optimise or completely re-design their processes. Although information technology is widely agreed to potentially contribute to cost reduction and efficiency improvement, the real success factors will be the radical re-definition and automation of processes: *Business Process Re-engineering* and *Workflow Management*.

The general benefits of introducing information technology, i.e. connecting imaging modalities to PACS, RIS and HIS, have been extensively discussed. A new technology basis, however, does not

*automatically* translate into process improvements. The access to digital information does not necessarily mean that work is organised more efficiently, or that services are improved. The integration of systems for the exchange of *data* has to be complemented by the integration and automation of *processes*. In the following we will discuss the workflow perspective of system integration.

## 8.3 A Workflow-centered view on radiology

Moving from film-based to digital departments, processes will unavoidably change. We need information systems which help to manage these changes and

- support the key processes in medical institutions,
- support the radical re-engineering and the automation of processes to meet economic and medical needs, and
- allow the flexible modelling and optimisation of processes, and
- the enactment of automated processes

Looking at processes is an important pre-requisite for system architects, designers and developers of systems to constantly keep the end-users perspective in consideration and provide products that really help to optimise the routine daily work. Even more, in the future we envision systems that keep formal process models and enact them at run-time: *Workflow Management Services* that are an integral part of medical IT solutions. This will be discussed at the end of the chapter.

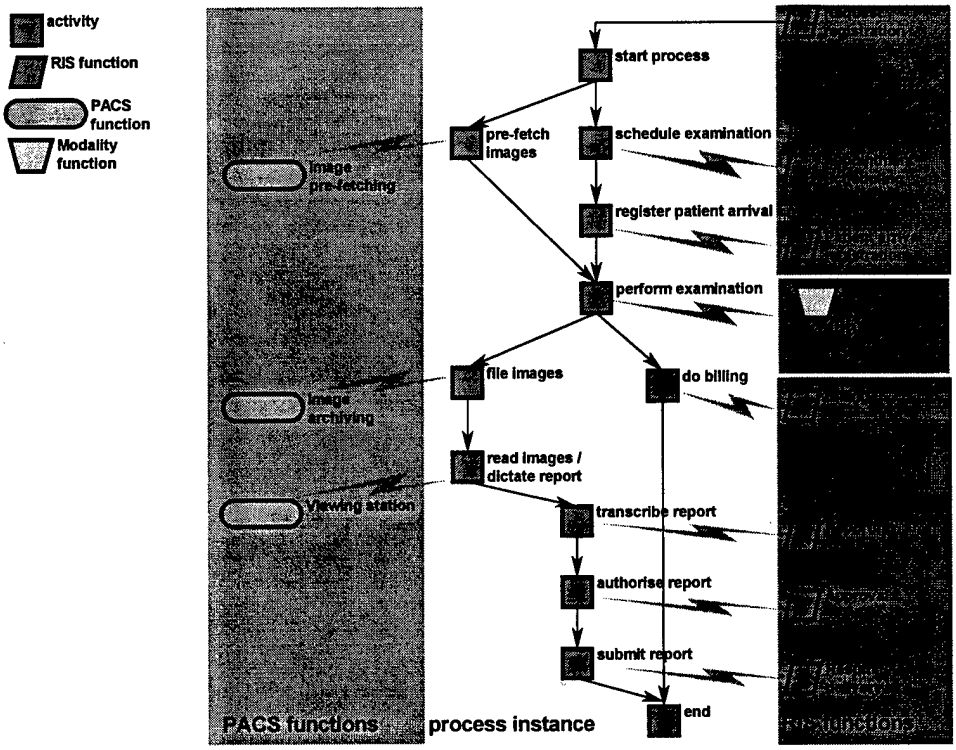


Fig.5.1: Workflow-centered view on radiology

A typical workflow-centered view on radiology is shown in Fig.5.1. It depicts a (very abbreviated) process consisting of the typical activities that we find in radiology. Each activity is supported by specific application system components that are used by workflow participants. Patient arrival registration, for example, is a typical activity performed manually by radiology staff using the corresponding component of the RIS. Other activities will be automated: Image pre-fetching, for instance, is a typical PACS related component which can be automatically invoked without human interaction. Fig.5.1 illustrates that processes do not stop at the boundaries of application systems. There are no PACS- or RIS-specific processes. Supporting processes means to consider *all* activities in an institution, and integrate *all* involved application systems. Workflow management solutions have to be independent of PACS, RIS, and modalities, specifically in multi-vendor environments. Thinking even further, we should keep in mind that processes in radiology represent only one service in a healthcare enterprise. Technology to support processes

has to be scalable at least to the enterprise level, if not to the level of the entire health care system.

### 8.4 Process integration in digital departments: Where do we stand today?

In a world of film/paper-based documents, the physical data entities (e.g. paper records, film folders etc.) serve two purposes: They are information carriers and act as tokens that are passed around to indicate which activity has to be performed at a certain location and specific point in time. They implicitly describe the status of work in progress. Piles of items represent worklists (e.g. a pile of film folders in front of a light-box may be the equivalent of a 'reporting worklist'). The disappearance of such physical control mechanisms in a digital department requires novel techniques to deal with the organisation of work.

The central part in Fig.5.1 depicts the modelling and enactment of the entire process in a department. This is not well supported by today's digital radiology environments. Currently we see workflow aspects being dealt with in *projects* rather than in *products* that would support this important aspect of system integration. Modelling aspects are normally spread over the entire information system environment. PACS implementations, for instance, keep models for the distribution and pre-fetching of images, while RIS vendors may rely on an internal model to automate part of the RIS-related activities in radiology. The separation of these workflow mechanisms has a number of clear drawbacks, such as

- preventing an overall and integral view on processes
- causing overlap of the existing workflow functionality implemented in the various sub-systems, especially in multi-vendor environments
- preventing an adaptation to the needs of different departments (process re-engineering and optimisation)

Current information systems in radiology were not explicitly designed to support the re-engineering or execution of the essential processes. What we have achieved so far is the integration on the data level: We have working standards supporting data exchange, and the improvements of DICOM over the past few years are a good example for this. This 'data-driven' standard offers little support for processes, and we have seen only few attempts to extend DICOM in this direction (e.g. supplements for Modality Worklist or Performed Procedure Step). These

extensions offer no *general* solutions that would meet future requirements for process integration.

How could a general solution look like? A logical demand is the implementation of *autonomous Workflow Management Services* as added to the data-oriented RIS and PACS services. This would provide

- comprehensive and integral management of processes
- independence of workflow from RIS and PACS manufacturers
- easier integration of optimal processes in multi-vendor systems

Moving forward from isolated image management to integrated workflow management will be the important next step in system integration[12].

### 8.5 A view on radiological processes: Generic activities in a typical department

What kind of processes do we find in radiology, and how can they be modelled and automated? From a general perspective, processes consist of logical sequences of typical activities. Table 5.1 depicts most frequently occurring *generic activities* in a typical department. These activities are generic in the sense that they are found in almost all radiology services worldwide.

Processes in radiology exhibit a considerable amount of variation among departments dependent on local circumstances. The actual sequence of generic activities may vary according to local preferences, laws, the installed technical infrastructure, or other factors. For Instance, different processes may be installed according to given examination types, type of patient (e.g. in- or outpatient), requesting department, current clinical question, patient's state of disease, weekday (e.g. changing services on weekends), or time of the day (e.g. different process for night/day-time).

There are many examples for variations: The sequence of activities may be different (e.g. conferencing may be done before report generation). Some activities may not be present at all (e.g. pre-examination viewing, pre-fetching, pre-loading, or report authorisation). Activities may be automated or performed manually by workflow participants. Fig.5.2 shows a typical example process consists of a number of the mentioned generic activities.

## 8.6 Process automation (workflow management)

An important issue for digital radiology is the radical re-engineering of processes to meet medical and administrative needs, and the automation of critical activities. Especially process automation can influence the key performance parameters such as timeliness, cost-effectiveness and quality of radiological services.

Which activities in radiology can be automated? Referring to table 5.1, some suggestions are made for the automation of generic activities. Aspects of automation include

- the automatic update of worklists by a workflow management service (automation of process enactment as a whole)
- the automation of all PACS-related activities previously performed by file room staff (e.g. filing, retrieval / pre-fetching / pre-loading, or transport of images and patient records)
- the automation of RIS-related activities (e.g. automated appointment scheduling), or automatic transcription of dictated reports
- the automatic invocation of application system specific services (e.g. co-operative user interfaces through automated pre-arrangement of images on a workstation screen, based on a default display protocol service)

In general, processes can only be modelled and automated if they are repeatedly performed in the same way, i.e. if they have a distinct structure. In radiology we find the whole continuum of processes from extremely structured to completely unstructured (ad hoc activities), which is expressed by examples in Fig.5.3. We find - similar to workflow applications in other service-oriented areas (like banking or insurance companies) - that most processes in radiology have a highly *structured* character. This holds particularly for the frequently and routinely performed examination types with high volume production (e.g. chest exams). As a guess, approximately 80% of the examinations may be classified like this, a good basis for the application of workflow management principles.

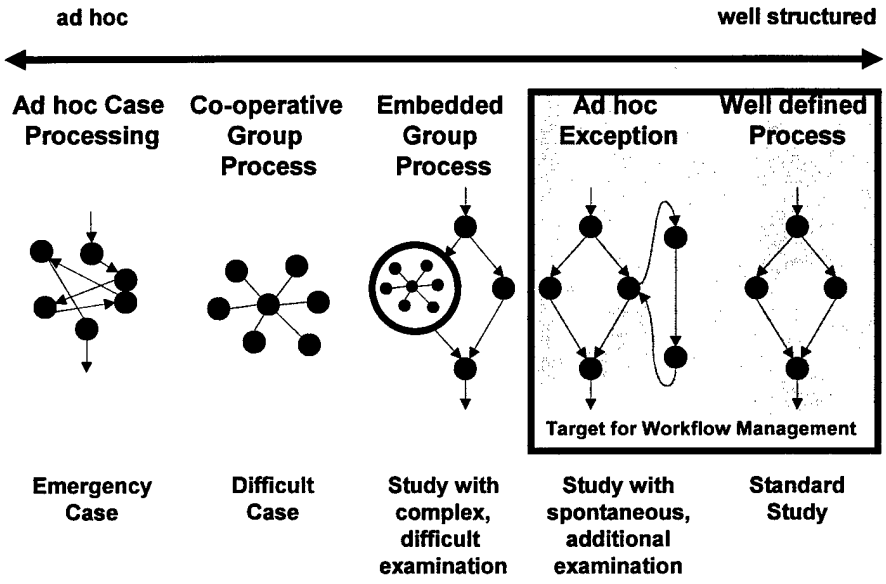


Fig.5.3: Examples of the radiological 'workflow continuum', ranging from highly structured to ad hoc processes.[13]

As typical for the medical domain in general, we also find a considerable amount of ad hoc actions being taken by radiology staff. Work is influenced by organisational and medical events, forcing the users to change, extend or discontinue the usual procedures. In emergency radiology, this is even the normal way of operation. As unstructured ad hoc actions cannot be modelled or automated, we need groupware concepts in addition to the workflow management aspects of work.

In the next paragraphs we address the technology which will enable us to implement process automation: Workflow management systems. We will also discuss how these systems can be integrated into the RIS/PACS/modality-world of radiology departments.

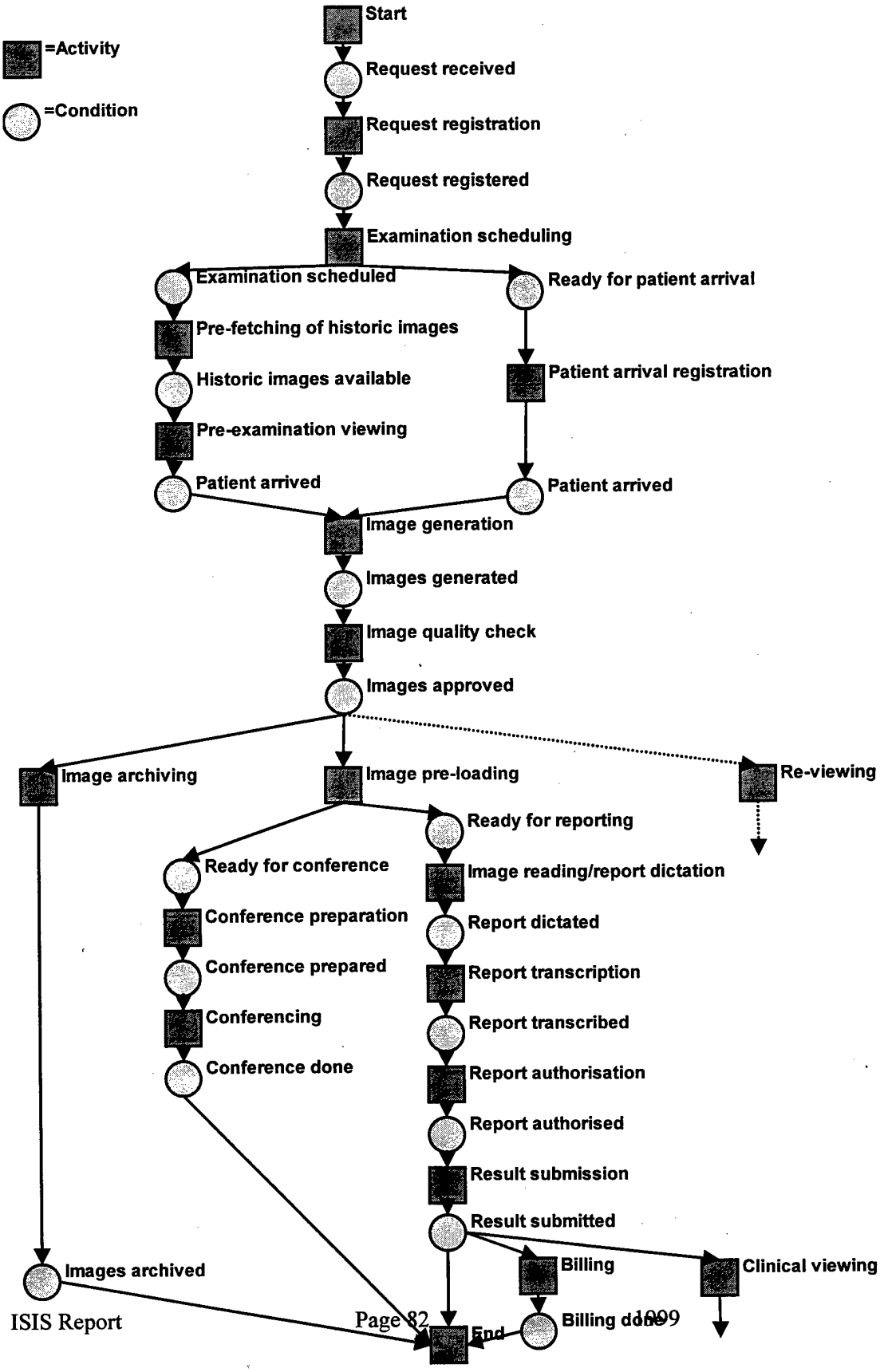
=Activity
=Condition
Start
Request received
Request registration
Request registered
Examination scheduling
Examination scheduled
Ready for patient arrival
Pre-fetching of historic images
Historic images available
Patient arrival registration
Pre-examination viewing
Patient arrived
Patient arrived
Image generation
Images generated
Image quality check
Images approved
Image archiving
Image pre-loading
Re-viewing
Ready for reporting
Ready for conference
Image reading/report dictation
Conference preparation
Report dictated
Conference prepared
Report transcription
Conferencing
Report transcribed
Conference done
Report authorisation
Report authorised
Result submission
Result submitted
Billing
Clinical viewing
Images archived
Billing done
End

Fig.5.2: Example of a typical radiological process

## 8.7 Looking to the future: Architectures for workflow management (WfM) in radiology

To be in control of a radiology department's processes, the use of Workflow Management Systems and the definition of workflow architectures was proposed[14,15,16]. In other service-oriented areas with a high emphasis on cost-effectiveness and efficiency (like insurance companies or banking), this technology has already proven its usefulness. We are now concerned with the question how WfM can be applied in the medical domain.

Workflow management concepts lend themselves to the work of the Workflow Management Coalition (WfMC) and are elaborated in depth in[17,18,19,20]. Following these documents, a workflow management system provides means to (Fig.5.4):

- model the organization in terms of organisational units and workflow participants
- model the processes in terms of activities and state-transitions
- match workflow participants and activities
- put processes into action and provide worklists for the application systems

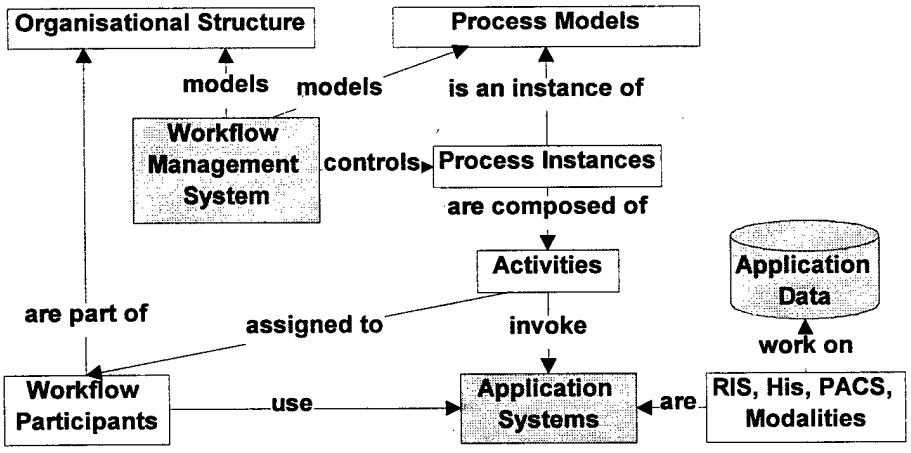


Fig.5.4: Workflow management concepts

WfMSs come with 'build time' and 'run time' components: The graphical *Model Editors* (for process- and organisation models) and the *Workflow Engine* with interfaces for connection to the required application systems. The workflow enactment service will provide the worklists for all attached application system components. Standard interfaces (s. next paragraph) will allow to query work lists, process work items, and invoke applications. Flexible queries allow for the building of worklists for the various work situations in radiology.

How would a workflow management service fit into a typical radiology IT environment? In the imaging domain, we have to deal with the three autonomous but interacting application systems (as illustrated in Fig.5.1):

- ***Imaging modalities***, with application functions for image production.
- ***Radiology Information Systems (RIS)***, with databases for administrative and medical data, and application functions to manage, visualise and process these data. (connected to HIS).
- ***Picture Archiving and Communication Systems (PACS)***, with databases for image- and image related data, and application functions to manage, visualise and process image data.

What we want to add are ***Workflow Management Systems (WfMS)***, with data bases for process- and organisational models and process related data, and functions to define and to build instances of processes, and to invoke other application systems at process execution time. WfMSs represent another service, a ***Workflow Enactment Service,*** in addition to the existing data-oriented services.

## 8.8 Proposed workflow interfaces and workflow-enabled application systems

For the existing data-oriented services, DICOM is the established standards in use. As mentioned earlier, DICOM offers little support for workflow services. Concerning workflow interfaces, we refer to the definitions given by the Workflow Management Coalition Reference Model[19,20]. The interfaces proposed for standardisation include:

- **Workflow Definition Interchange (Interface 1):** The interface between the modelling and definition tools and the runtime workflow management software.
- **Workflow Application Programming Interface (Interface 2):** This interface provides access from a workflow application to the Workflow engine and to worklist.
- **Invoked Applications Interface (Interface 3):** Invocation of applications being activated directly by the workflow management system (with no workflow participant being involved). (recently merged with interface 2)
- **Interoperability Functions (Interface 4):** Runtime support for the interchange of various types of control information, to transfer workflow relevant and/or application data between the different enactment services (e.g. between the hospital's overall workflow enactment service and the radiology service)
- **Administration & monitoring Interface (Interface 5):** Interface of management applications interacting with different workflow domains for the purpose of User Management, Role Management, Resource Control, Process Supervisory Functions, etc.

These standards have recently been adopted by the Object Management Group (OMG) and promise to gain importance in the near future.

For the future we require application systems to fit into workflow architectures. These *'workflow-enabled application systems'* will need – in addition to data-oriented services provided via DICOM interfaces – connections to the department's workflow enactment service via workflow interfaces. The Workflow API (interface 2 of the WfMC is functionally the most important one to be mentioned)[21]. The principle proposed structure of a workflow enabled application system is shown in Fig.5.5. The next step needed is a principle agreement (standard) on workflow architectures among the providers of radiological application systems.

This will be a pre-requisite to support the entire radiological process and make this concept work in a multi-vendor environment.

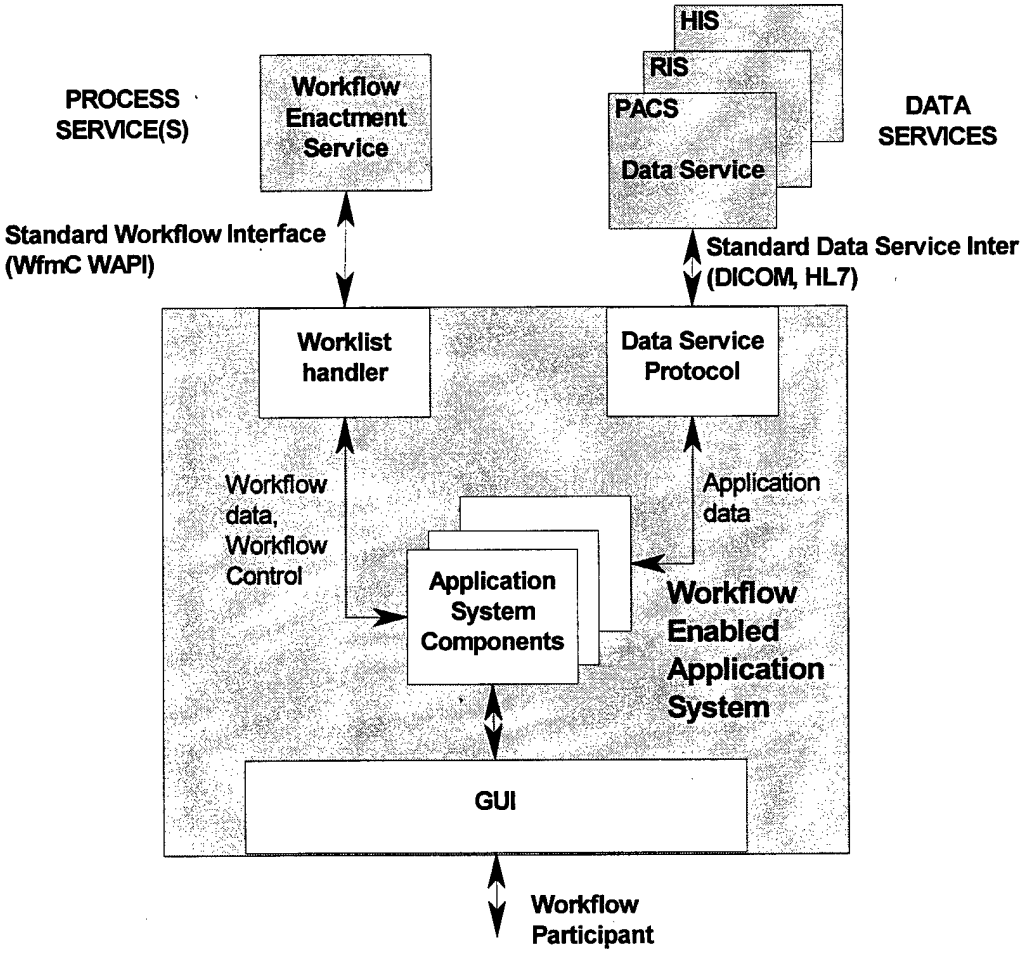


Fig.5.5: Workflow-enabled application systems

| Generic activity | Typical workflow participants | Typical locations | Typical application system |
|---|---|---|---|
| 1. Pre-visit administration | | | |
| Request registration | Secretary | Office | RIS |
| Examination scheduling | Secretary | Office | RIS |
| Information pre-fetching | (automated) | - | PACS |
| Patient arrival registration | Receptionist | Reception | RIS |
| 2. Image generation / examination | | | |
| Pre-examination viewing | Radiologist, radiographer | Exam room, anywhere | Modality WS, SCD-WS, any WS |
| Image generation | Radiologist, radiographer | Exam room | Modality |
| Post-examination image quality check | Radiologist, radiographer | Exam room, reading room, anywhere | Modality WS, SCD-WS, any WS |
| 3. Post-exam administration | | | |
| Image pre-loading | (automated) | - | PACS |
| Image archiving | (automated) | - | PACS |
| 4. Image reading and reporting | | | |
| Image reading | Radiologist | Reading room | SCD-WS |
| Report dictation | Radiologist | Reading room | RIS / Dictation system |
| Preliminary report generation | Radiologist | Reading room | RIS |
| 5. Post-reporting administration | | | |
| Report transcription | Secretary (automated) | Office (-) | RIS / Speech recognition system |
| Report authorisation | Radiologist | Office, reading room, anywhere | RIS, SCD-WS |
| Result submission | (automated) | - | RIS / PACS |
| Billing | (automated) | - | RIS / HIS |
| 6. Post-visit image re-viewing | | | |
| Conference preparation | Radiologist | Conference room | Conference-WS, any WS |
| Conferencing | Radiologist | Conference room | Conference-WS |
| Clinical viewing | Referring clinician | Clinical dept. | Clinical WS |
| Radiological re-viewing | Radiologist | anywhere | SCD-WS, any WS |
| Teaching | Radiologist | Conference room | any WS |
| Non-clinical viewing | any physician | anywhere | any WS (Wendler 3/99) |

Table 5.1: Generic activities in radiology processes with typical workflow participants, locations and application system.

## 9.0 Conclusion

PACS is not the only information system in a health care enterprise. Historically, it has emerged as a separate discipline in the domain of radiology and an isolated field of development, caused by initial technology limitations in storing and handling large volume image data objects. Also the other systems in the domain (RIS, modalities, speech recognition systems, etc.) have initially been developed as autonomous solutions, driven by different communities.

For many medical and administrative reasons it is essential to share the information among the various systems. We have discussed the necessity of data integration and some of the important practical issues in this field, such as the ownership of data, the mechanisms of information passing, and the options and trade-off for various connectivity approaches. Fortunately, vendors have moved closer to integrated solutions over the past few years, supported by maturing data exchange standards (DICOM, HL7). From today's point of view, integrated solutions are urgently needed to facilitate IT projects in hospitals. For the future we envision truly integrated systems where the users' point of view - to work with one coherent information system - is reflected by system architecture and implementation. This kind of integration will not stop at the boundary of radiology departments, but will finally deal with entire health care enterprises or even the health care system as a whole.

Integrated *data* services and the flow of data between sub-systems represent just one aspect of system integration. Another aspect we have discussed is the integration of *workflow*: Information systems have to support the essential processes in health care enterprises, and much more attention has to be given to the design and enactment of processes. In a world of shrinking health care budgets, increasing cost pressure and growing demands to improve the quality of services, health care institutions are forced to radically redesign and – where possible – automate parts of their processes. In the past, integration efforts have focussed on data integration, and process aspects were dealt with in expensive projects rather than in products.

We envision this to change in the future. We have taken a workflow-centered view on radiology, discussing the nature of processes

and options to model and enact them. To better support the workflow aspect of system integration, we have proposed to use Workflow Management System technology and to provide autonomous workflow management services in addition to the established data services. This would enable radiology departments to design, optimize and control processes to meet their medical and economic needs and to stay competitive. In addition to data standards (DICOM, HL7) workflow standards have to be established and implemented, and DICOM compliance on the data level has to be complemented by appropriate workflow-enabled application systems. Again, this approach has to be scalable to the enterprise level.

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# CHAPTER 6

# A COMPUTERIZED IMAGE MANAGEMENT AND COMMUNICATIONS (IMAC) SYSTEM IN DIAGNOSTIC IMAGING

## 1.0 Information Management in a Hospital

Health care is an information intensive industry that requires rapid and accurate data collection, distribution and management. A hospital generates a staggering amount of data to support many specialized services. Currently, there are many redundant manual and semi automated information management activities to support the most immediate requirements in the various functional units. Rapid changes in the health care environment demand different types of information management capabilities, but it has been difficult to meet the changing needs. Figure 1 illustrates current state of confusing health care information systems consisting of both manual and computerized activities. A hospital information system can be grouped into six major functions; medical records, financial system, management system, patient information system, radiological imaging service and educational research network. Some functions overlap and others have complicated information exchanges. A common response to the information management problem has been a development of specialty information sub-systems for immediate and short-term benefits. These sub-systems optimize the functions of the area for which they are developed with little regard to overall institutional efficiency. The need for a fully integrated information system has been well known for many years. But poor connectivity in medical devices and lack of affordable key technologies coupled with the high cost of a specialized product for a limited medical market have hampered any seamless system integration for the hospitals in the past.

This paper addresses mainly radiology Image Management and Communication System (IMAC) in the context of hospital-wide patient care activities. An example of filmless radiology initiative at a new hospital as well as problems associated with transitioning from conventional radiology to filmless radiology environment will be described. It will then be concluded by offering some ideas how one may develop a medical network that can support film-independent and paper-independent hospital in the future. Some detail and specific data on operational aspect of radiology service within a hospital are described for those readers who may not be familiar with radiology.

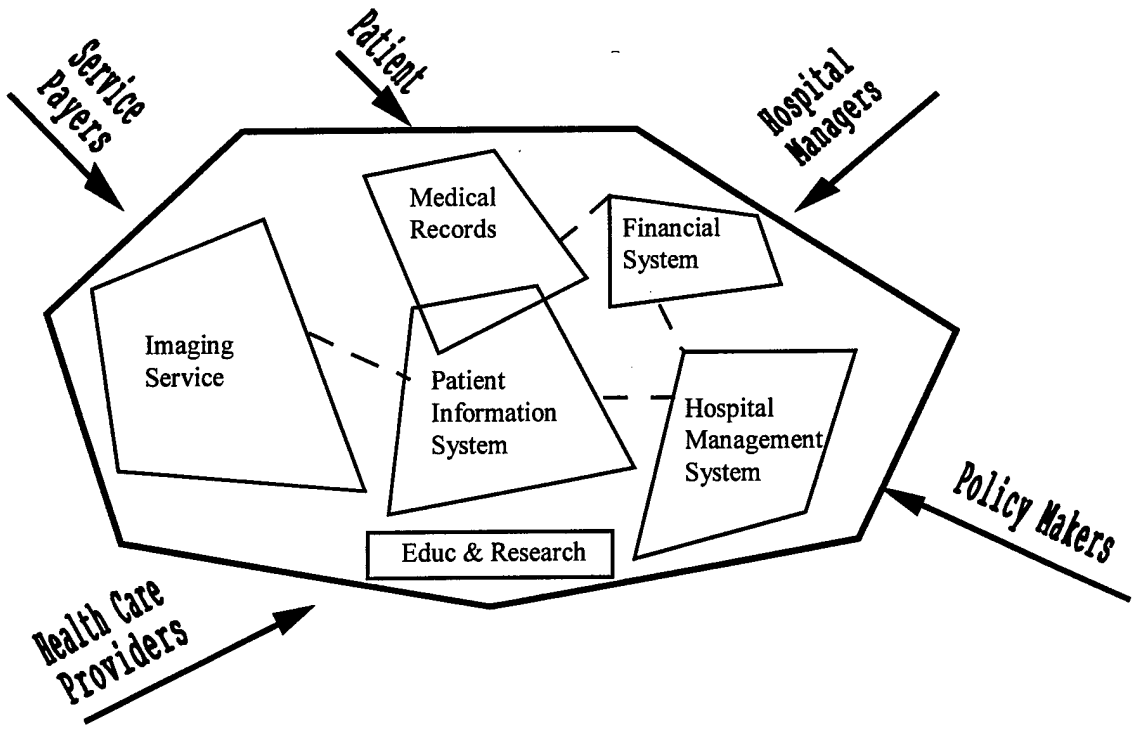


**Figure 1: Current health care information system**

Communication and coordination costs typically account for 25% of a hospital's operating expense, and there are endless small manual tasks that everyone has to do to keep the hospital running. If one follows a typical hospital based physician making clinical rounds, one will see that the physician's activity is composed of two different steps, (a) working directly to analyze and treat the patient and (b) information gathering [1]. Historically the physician gathering information would have to go from the bedside to the chart to read the nurse's notes, to the phone to call the laboratory to gather accurate, up to date clinical laboratory values and to the radiology department to review the x-ray images with or without the radiologist. The generation of written reports is too slow, and the phones are generally inefficient for gathering information. This disseminated location of the needed information means that the physicians do not ever have all the information together at the patients bedside in a timely fashion. The physician has to d e p e n d o n the notes he makes as he rounded on what each support service said, and because this is not a written report, does not know whether or not the final report might differ. At each step in gathering information, the physician would encounter the frustration of needing to wait while the information is retrieved for review. In some cases, written reports of laboratory values and x-ray reports have been printed on the patients unit, but are often not placed in the patients chart in a timely fashion (delays of 12 to 24 hours are common) and the x-ray images are still in the radiology department.

The physician seeing a patient at a small outpatient facility faces complementary problems. This physician, in her office, sees patients and sends them for laboratory tests, consultations, and radiological examinations or alternatively obtains these in her own facility. The radiologist is elsewhere. Either the primary physician evaluates the images herself (at an overall lower skill level than would be provided by a radiologist), or sends the images elsewhere for complete interpretation. This delays the availability of the information and means that the patient may have to make an extra visit to the primary physician or discuss the findings with the physician over the phone. This is also inefficient. If all the information from the tests could be gathered while the patient is still in the primary physicians office, efficiency would improve the patient would be more satisfied by having a more immediate answer, and the quality of care would likely be better because the primary physician would have all the needed information while the details of the patients complaint were still fresh in her mind. The ideal would be to have all the required information needed for diagnosis available the same day, discussed with the patient, and definitive treatment started.

## 2.0 Radiological Imaging Service

Approximately 70% of patients coming to a hospital require some form of diagnostic examination. Efficiency and quality of radiological service are major and integral parts of patient care in a hospital.

### 2.1 Role of Radiology Study in Patient Care

A simplified sequence of cancer management activities, as an example, is shown in Figure 2 to illustrate the general role of diagnostic service with respect to the rest of the patient care activities. Once a cancer is suspected, the patient together with a physician must decide whether or not to enter into diagnostic tests. There are many imaging modalities. Types of radiological exams and sequence of studies often are decided between a radiologist and a referring physician.

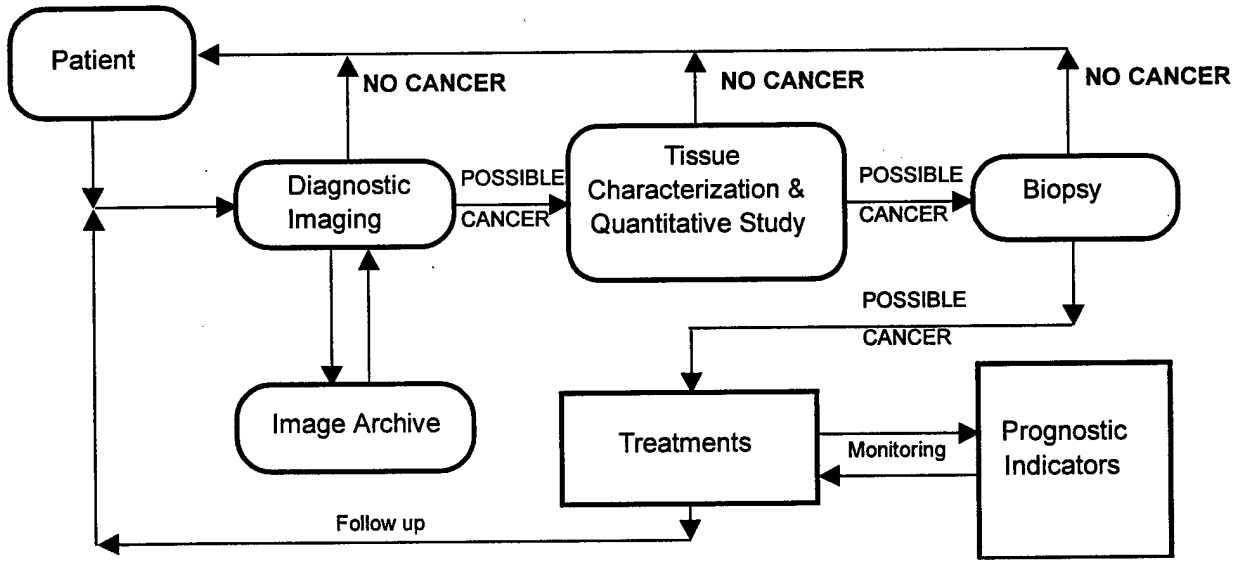


**Figure 2: Role of diagnostic imaging**

Since new imaging methods are available now, the quality of diagnosis has improved dramatically over the last decade. In the case of imaging, having prior images and reports available decreases the number of biopsies that yield benign disease. Review of previous exams

stored in image archive is an integral part of radiological diagnosis. Often in some facilities up to 20% of prior exams (films) cannot be located. If the diagnostic study shows possible cancer, prior to a biopsy, additional tests might be ordered. In the case of mammography, abnormal readings resulting in biopsy occur in up to 5% of mammograms. Of these only 1 in 5 is due to breast cancer. Increasingly, images can be processed to distinguish cancerous tissues from benign tissues. Newer techniques in tissue characterization can decrease the number of biopsies that find benign disease, thereby decreasing cost and patient anxiety. If cancer is confirmed, appropriate therapy is ordered. During the course of therapy, prognostic indicators can point to the most effective treatment for biopsy confirmed cancer. A great deal of research is directed to improve these indicators for the correct selection of therapy.

## 2.2 Baseline Study of Radiology Service

Radiology services pose one of the most difficult problems of information management because they generate large amounts of data [2,3] recorded on film, which is an expensive and inflexible medium, and they must be managed rapidly and reliably for many competing users. On a single day, a radiology department like Georgetown's may handle more than 300 patients and 5,000 sheets of film, including both old and new images. The management and distribution of radiology information and radiological images are responsibilities of the radiology department. Over the past two decades new imaging technologies such as magnetic resonance imaging (MRI), x-ray computed tomography (CT), single photon emission computed tomography (SPECT), positron emission tomography (PET), computerized radiography (CR), digital subtraction angiography (DSA), and ultrasound (US) have given the radiologist a powerful set of new diagnostic tools. Unfortunately, the quality of service in the radiology department has not experienced similar revolutionary improvements over the last decade.

In fact, the use of many varying imaging modalities has imposed additional difficulties in the management of films and data because:

(a) they are often produced in distant locations,
(b) images are presented in a variety of film formats,
(c) radiology service has become highly subspecialized causing a greater need to review multimodality images, and
(d) within large and complex medical care facilities there is an increasing number of competing demands for radiological images.

A characteristic information flow [4] is highlighted in Figure 3. A 450 bed, teaching hospital such as Georgetown University Medical Center conducts approximately 120,000 radiological procedures per year. The department of radiology which includes general radiology, MRI, CT, ultrasound, nuclear medicine, angiography, interventional radiology, pediatrics, mammography and bone radiology and has twenty-four full time radiologists, eight imaging physicists, fourteen residents, eighty technologists, and twelve transcriptionists. The department has three film libraries where the imaging studies are stored: an active file in the middle of the department, a recent file (containing images from the previous eighteen months) at the remote part of the department, and a long term archive (containing images from the previous five years for adults and from the previous five or more years for pediatric cases) 10 miles away. In a teaching hospital each image is likely to be recalled from the film library at least two times, and often three or four times within the first 36 hours after it is obtained.

Solid lines represent the flow of films while dashed lines represent the flow of reports. Information and data flow is a labor-intensive procedure that is increasingly expensive and at times impossible to maintain. One of the most common problems a radiology service may have is lost films. In a survey [4] at Georgetown, approximately ten percent of requested images c o u l d

**General Overview of Radiology Service**
**(Information Flow Patterns)**

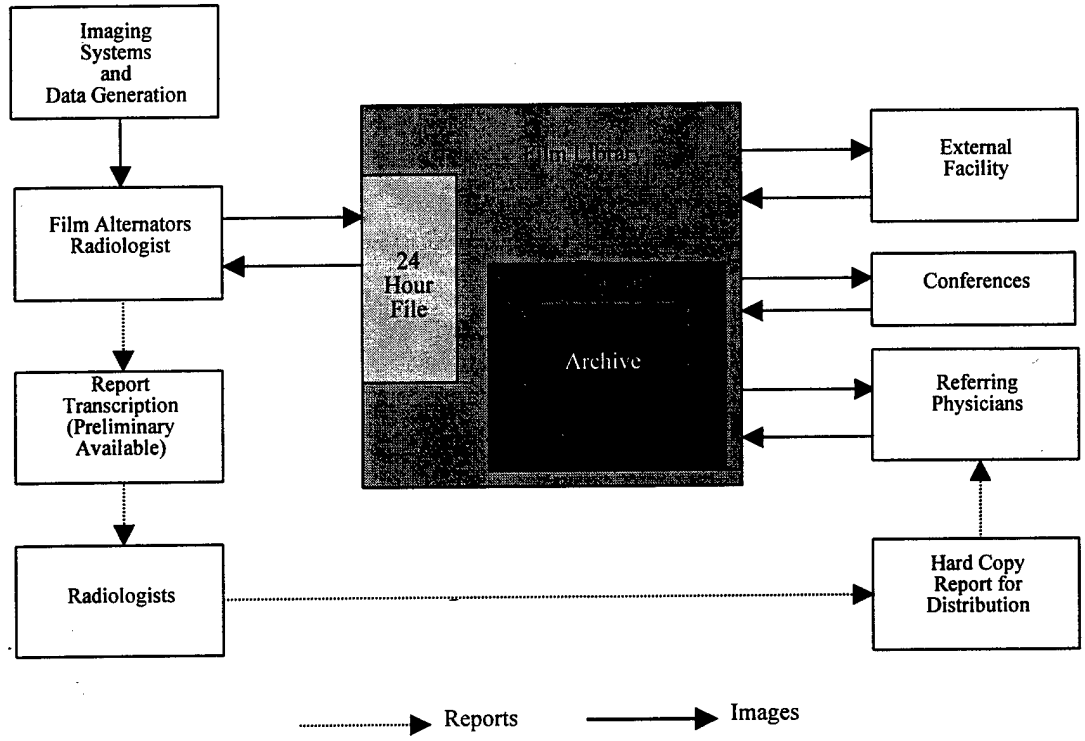


**Figure 3: Characteristic information flow in radiology**

not be located in the film libraries. Solid lines represent the flow of films while dashed lines represent the flow of reports. Information and data flow is a labor-intensive procedure that is increasingly expensive and at times impossible to maintain. One of the most common problems a radiology service may have is lost films. In a survey [4] at Georgetown, approximately ten percent of requested images could not be located in the film libraries.

From the viewpoint of referring physicians, diagnostic reports are the final products of radiology service while the referring physician is the customer of radiology service. What the referring physician desires is the timely provision of diagnostic reports. Therefore, report turn-around time is a good measure of the quality of radiology service. The average time-lapse between the transcription and report signing of one hundred reports has been found to be just over three days.

Because radiologists manage the running of the radiology department, the patterns developed for the management of radiological images reflect best the needs of the radiologists rather than the true customers of the radiology department i.e., the patients and the referring clinicians. The centralization of radiological images helps to improve the radiologist's efficiency, even though it may adversely affects the efficiency of the clinician who refers patients to radiology. In many hospitals, there is conflict over the control of the radiologic images with demands for decentralized storage so that they are available to the clinician at the bedside or to the physician in the emergency department. This demand is most prominent from the physicians managing intensive care units (since they often cannot leave the patient's bedside) and from

orthopedists who need the images in front of them to evaluate the patient's pain or to treat the patients fracture.

Difficulties in the management of radiology films throughout a hospital are a constant source of frustration for many. The conventional approach of adding more people, space, and money to solve these problems has not produced satisfactory results. It is doubtful that the radiology department can afford to continue to function in a predominantly manual mode for many more years. A new approach using computer and communication technology could provide a possible solution to the radiology community.

## 3.0 Potential Solutions: IMAC Network

A new concept that is gaining momentum to address this image management problem in radiology is the Imaging Management and Communication (IMAC) system [5,6], also known as Picture Archiving and Communications System (PACS); a network of computer-based digital imaging and information devices designed to manage medical diagnostic service. IMAC will significantly improve the quality, productivity, and efficiency of radiology service.

An IMAC network system consists of 4 major subsystems:

(a) Image Acquisition Subsystem
(b) Image Display and Workstation Subsystem
(c) Image Database and Storage Subsystem
(d) Communications Network Subsystem

The image acquisition subsystem includes digital radiography systems, film digitizers, and interfaces to standard digital imaging devices. The image output and display subsystem includes hard copy laser printers and image display workstations for primary image interpretation and secondary clinical review. The image database and storage subsystem require a database management system for image and data storage. The communication subsystem connects all of the components and moves both images and text data from one unit to another. Figure 4 indicates a conceptual configuration of a general IMAC network.

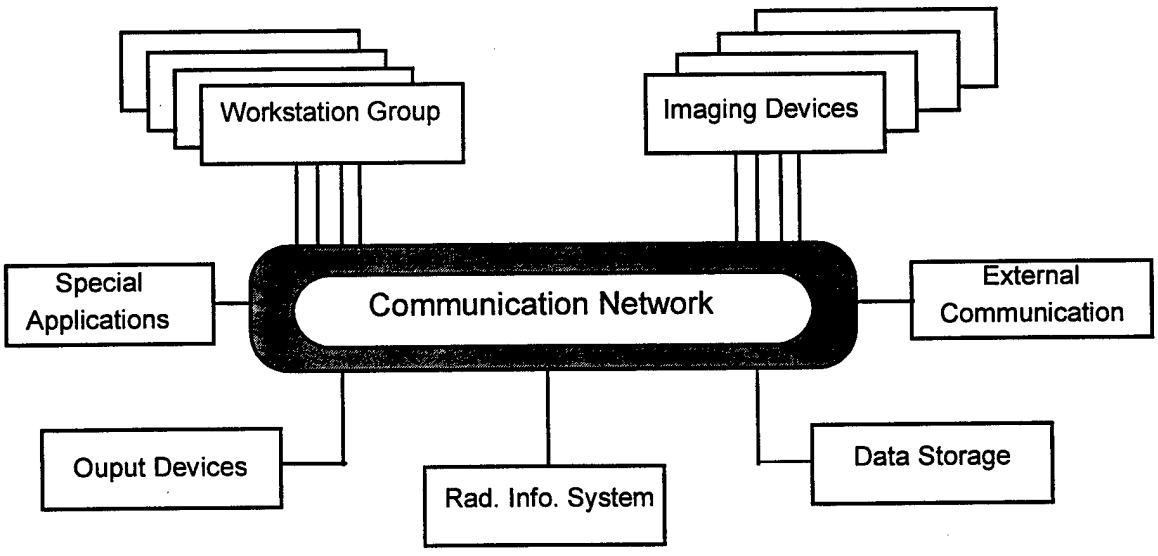


**Figure 4: Conceptual Image Management and Communication (IMAC) Network**

### 3.1 Digital imaging systems

Many medical imaging systems such as x-ray CT, MRI, SPECT, and PET are already in digital form. These digital images constitute approximately 30% of the total volume of images produced in a radiology department. The remaining 70% of images include conventional radiographs on films of the chest, skeleton, abdomen and GI tract. Unless one develops a different method of handling these conventional films, global improvement in productivity in image management and radiology service throughout a hospital cannot be achieved.

Currently, there are two methods of producing digital information representing these conventional analog images for IMAC: film digitizers [7] that scan conventional films, and computerized radiography (CR) that captures x-ray images using storage phosphor plate [8, 9,10,11] that is subsequently scanned by a laser beam. However manufacturers are beginning to introduce a direct digital radiography (DR) system based on flat panel of x-ray array detectors replacing conventional film/screen cassette [12]. Since DR is at an early phase of clinical application, the technology will not be discussed here.

A laser film digitizer functions by scanning a conventional x-ray film image with a focused laser beam and recording the amount of light transmitted by the film. Film digitizers are indirect means of acquiring digital images because they depend on a conventional x-ray film image for primary imaging. Film digitizers also depend on the transmission of light by the film, causing the reversal of the signal to noise characteristics. Dark areas of film represents capture of more x-ray photons by the film, meaning less quantum noise, but when the film is digitized, small number of photon get through the darker area, causing increase in random noise within the darker region of the image. There is not enough data to show the effect of such noise characteristics to image viewing.

A relatively new digital radiography system known as CR enables the direct acquisition of radiological images. Computed radiography system uses photostimulable luminescence as a primary image receptor. The computed radiography systems utilize a cassette similar to a conventional radiography cassette except for the fact that the film/screen system of conventional radiography has been replaced by the reusable phosphor imaging plate. The cassette is similar to that used in conventional radiography so that no retrofitting of existing x-ray equipment or exam rooms is necessary. The exposure latitude of the phosphor plate is extremely wide when compared to that of film/screen systems. The phosphor plate's wide exposure latitude also makes CR ideal for portable chest exams in the intensive care unit (ICU) environment [13,14], which has traditionally suffered from under and overexposure and a resultant relatively high amount of retakes.

Within the CR plate reader, the image plate is removed from the cassette and passed in front of a scanning laser beam to liberate its latent image. The latent image is detected and recorded digitally, and the image plate is erased by exposure to bright light and the cassette with erased image plate is then returned to the x-ray technologist for reuse for another exposure.

Current computed radiography systems produce images with a nominal 2,000 x 2,500 (2k x 2.5k) matrix of pixels. For images acquired using a large phosphor plate (14" x 17"), this yields a resolution of approximately three line pairs per millimeter (3.0 lp/mm). Phosphor plates of smaller size (24 x 30 cm) can yield a somewhat better resolution of close to four line pairs per millimeter (4.0 lp/mm). As a comparison, conventional film/screen systems can obtain a resolution of approximately six line pairs per millimeter (6.0 lp/mm) for chest films. The line pair resolution is the result of the use of x-ray grid, not the resolution capability of the film. The grid is used to reduce the scatter (and thus improve the contrast) of x-ray beams caused by the patient.

## 3.2 Workstations

In a filmless imaging environment, diagnostic images are viewed on cathod ray tube (CRT) monitors driven by various workstations. At least three types of workstations are required; the diagnostic reporting station, the review station, and the special application workstations. The distinctions are made based on the use, the performance requirements, and the cost of the system. These distinctions are however becoming blurred as image display and processing technology is improving rapidly.

The diagnostic reporting station [15, 16] is primarily for radiologists and a few specialists to read new and previous exam images and generate diagnostic reports. This workstation should support simultaneous viewing of at least four 2,000 x 2,500 images with 10 bits of dynamic range on large monochromatic non-interlaced screens. Some MR and CT images have 12 or 16 bit data and the display processor should preserve the full dynamic range for processing and computation. It should be noted that image display (CRT) can display no more than 8 bits of gray scale. The station should have a set of highly interactive routines for image presentation and processing. The system should also have an integrated direct diagnostic report generating capability. This will make reports quickly available for distribution to referring physicians. Two key requirements for the workstation are display speed and sequence of image display. On a single day during a diagnostic reading session, a radiologist needs to view 200-300 sheets of images (2,000 x 2,500 x 10 bits per image). In the case of MRI and CT, it is common for radiologists to view more than 1,000 frames (256 x 256 x 12/16 bits per image) during a daily reading session. Display speed of 2 seconds per large image is called for currently. Every radiologist has a certain way of displaying multiple images of same studies obtained at different times and multiple images of different imaging systems. The relative location and order of display of particular images with respect to other images on multiple screen workstation (so called, the hanging protocol) must be predictable and logical to the radiologists.

The review workstation is primarily for referring physicians and for consultations rather than primary diagnostic reporting. It supports medium-resolution (1000 x 1200) displays with the ability to access both images and reports. These workstations can be located throughout the hospital and within the radiology department.

The number of display screens and images desired for simultaneous viewing [17] is an important feature for a diagnostic reporting workstation. Currently 40-100 images are presented to the radiologist simultaneously in the case of MR or CT and 4-8 images for chest and bone studies. This panoramic presentation provides enormous efficiency for the radiologist in obtaining the global diagnostic overview. It is essential for the diagnostic reporting station to provide this type of efficient image presentation capability. Stacked display of MR image series with synchronized rapid flipping through three or more stacks of slices (for example T1, T2 and proton-weighted MR slices) is now possible on low-cost workstations. The number of images for simultaneous presentation, image size, the overall dimensions of the image display devices, and image presentation capabilities have not been fully studied in a clinical operational environment.

The radiology image processing is done on three different levels: at the imaging systems, by the technologist to generate hard copy film images, and finally by the radiologist at the time of film viewing. The type of desired processing depends on the imaging modality. In every digital imaging system, sophisticated image processing operations are already carried out to generate optimal images on hard copy film. For example, radiography technique factors (i.e. x-ray beam selection) and film processors are set to produce a certain quality of diagnostic images. For chest radiographs the additional "image processing" is done by the radiologist at the film alternator in terms of hot lighting, squinting the eyes (smoothing), and magnification. These

processing [18,19, 20] capabilities at the technologist and radiologist level must be available at the workstation and must be automated according to a predetermined protocol.

Three dimensional image display is not a high priority in diagnostic radiology but is rapidly gaining the interest of radiologists due to ease of access to 3-D rendered images such as MR and CT angiogram on scanner's imaging console and on low-cost but powerful image processing workstations. Surgical planning and radiation treatment planning based on interactive manipulation of 3-D images have always been of great interest in radiation oncology and other special application areas.

### 3.3 Interaction with radiology information

The IMAC system requires several processes in addition to the imaging functionality. These include entry and use of patient demographic data, order entry functions, and results reporting that are traditionally handled by radiology information system (RIS). Interface of IMAC with RIS [21,22] avoids redundant manual entry of common data elements in the RIS and the IMAC databases for routine clinical operations at patient registration points, image acquisition sites, or display workstations. In some IMAC networks, an auto routing of images to workstations may be desirable to avoid data traffic bottleneck. A radiology exam order entered in the RIS for a procedure or procedures could prompt the IMAC image database to perform 'autorouting'. The RIS information can trigger the image database to initiate autorouting of (a) exam orders, (b) pre-interpreted image exams (c) post-interpreted archived image exams and (d) radiological reports, across the IMAC network. This autorouting may be targeted to specific acquisition and display devices, both in and outside of the radiology department according to site-unique, site definable/modifiable algorithms. Traditionally, the radiological reports are usually generated in RIS.

To referring physicians, who are the primary users of radiology service on behalf of their patients, the availability of radiological reports is often more important than the images by themselves. Missing reports, unsigned reports and separation of reports from the images are major problems today. Integration of convenient and efficient reporting capabilities with the IMAC workstation can reduce the frequency of occurrence of these problems. Integration of the reporting systems and the workstation will transform the IMAC from an image shuttling system to a complete diagnostic decision support system.

### 3.4 Data storage and system integration

Depending on system architecture, image storage [23, 24] may be distributed at several hardware components on the network. Storage devices could include magnetic tape drives, magnetic disk drives, as well as erasable and non-erasable optical drives and related magnetic and optical juke boxes and optical tape devices as they apply to medical imaging.

Images and related information that should be in the short-term storage are (a) exams that are newly acquired in the past 48 hours, (b) exams awaiting primary interpretation (c) exams acquired in a period equal to the facility's average length-of-stay for inpatients, (d) selected historical exams are needed at clinical areas according to a daily clinic appointment schedule, and (e) selected supporting historical exams of patients who have had new image exams.

The long-term archive should be capable of storing the current year plus 4 additional years of imaging exams for a total of 5 years of imaging exams. In the case of Georgetown University, we generate approximately 5 Terabytes per year, excluding mammography. Additionally, there are certain instances where exams must be retained more than 5 years- e.g., pediatric images must be retained until a patient's 21st birthday and some mammography exams

must be retained for the life of the patient.

External communication requirement will depend on the work load and work pattern of radiology service. For a small scale operations ethernet or 19.2Kbps modems are sufficient. As data volume increases, higher speed such as 100 Mbps or T-1 lines will be needed.

System integration in IMAC technology shares many of the generic problems in computer technology. In the past, most imaging devices were not designed to support network operations and in some cases certain manufacturers were reluctant to provide proper interface capabilities to move images. However the use of an interface standard known as Digital Imaging Communications in Medicine (DICOM) [25], developed jointly the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), has significantly improved connectivity and proper interface of new imaging equipment to IMAC network. The manufacturers of medical imaging equipment have widely accepted this standard and products can no longer remain competitive without providing such standardized interface to the IMAC network.

Data compression [26] is an important topic in radiology for it can improve network performance and reduce the data storage requirement. Many physicians feel that any lossy compression may contribute to erroneous diagnosis, while many scientific studies show that there is not any statistically significant difference in diagnosis even when the images have been subjected to 15:1 compression [27].

## 4.0 Samsung Medical Center Implementation of IMAC

A general description of a phased implementation of IMAC at a newly built hospital with the goal of providing hospital-wide filmless radiology services is described. Samsung Medical Center (SMC) is a tertiary hospital in Seoul, Korea and when the new hospital opened in October 1994 [28] the first stage of the IMAC environment was implemented to provide softcopy services to Orthopedics Surgery, Neurosurgery, Neurology, Intensive Care Units and Emergency Room. In September 1996, the second stage was implemented where considerable number of display workstations was installed to all the outpatient clinics and inpatient wards of referring departments. At the same time, a major system upgrade was carried out to increase the capacity of both the short-term storage and long-term archive as well as to interface all remaining imaging modalities. For the final stage, in December 1997, a separate image server was installed to distribute images to all 30 operating rooms, and with that a hospital-wide IMAC environment was achieved [29].

### 4.1 Imaging Modalities

All imaging modalities in the radiology department (except a mammography unit and a bone densitometry unit) are interfaced to a centralized image server: 7 CR readers, 3 MRI, 3 CT, 3 DSA units, 2 digital fluoroscopy units, 2 CR based fluoroscopy units, 9 US units and 2 film digitizer. Three film laser printers are also interfaced. Figure 5 shows a schematic representation of the installed IMAC equipment at Samsung Medical Center.

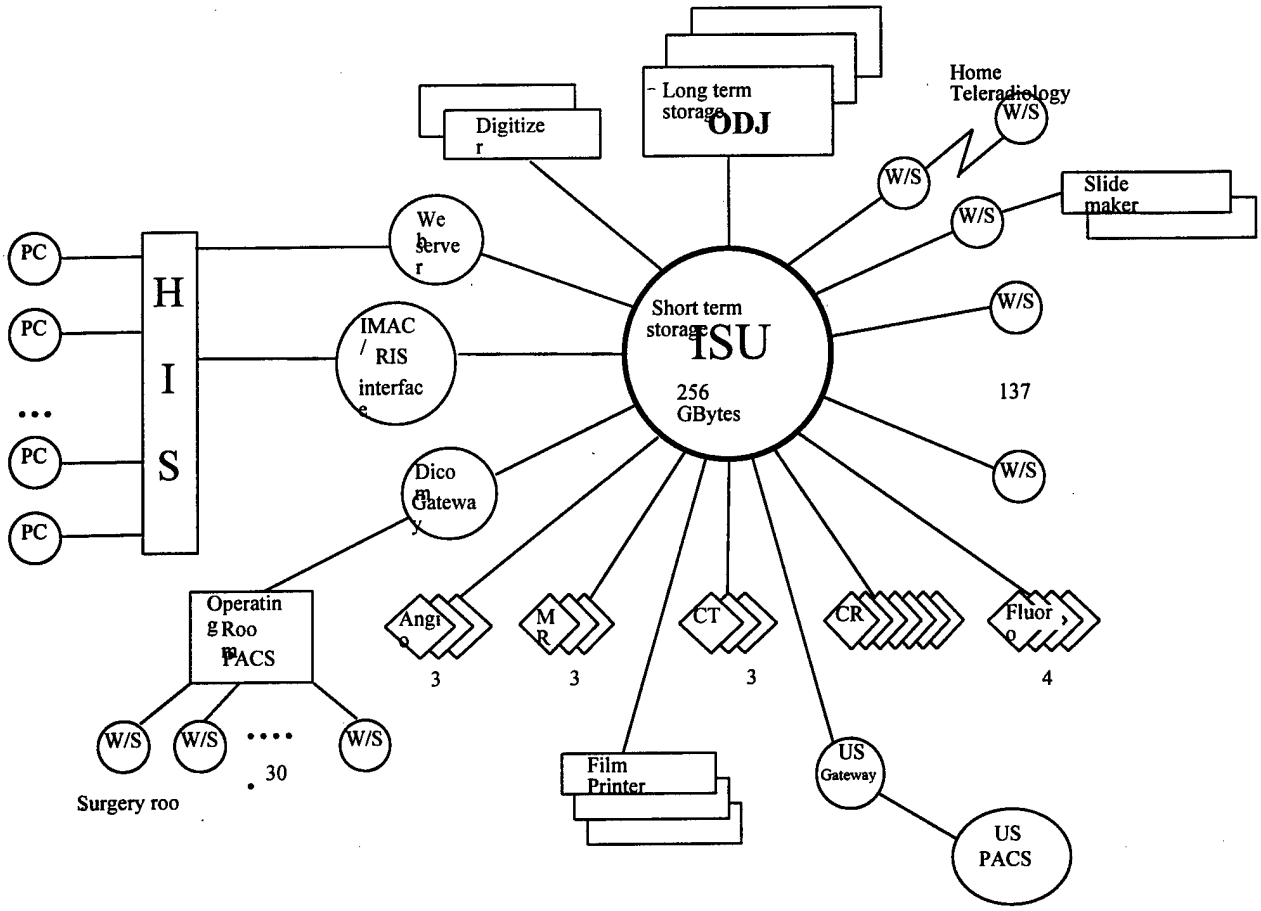


**Figure 5: System configuration of IMAC at Samsung Medical Center**

The acquired exams from the modalities are transferred to the main image server via various image gateways as shown in Table I. All ultrasound scanners are clustered onto a separate mini-IMAC network with a dedicated 20 Gbytes image server and 99 Gbytes (76 x 1.3 Gbytes) MOD-based long-term archive. US images are frame captured in color, converted to grayscale images and transferred to the main imager server (ISU) via a dicom gateway (see Figure 5).

| Modalities | Manufacturer/Model | No. | Mode of Transfer |
|---|---|---|---|
| MRI | GE Signa Advantage | 2 | GE Dicom Gateway |
| | GE Horizon | 1 | GE Dicom Gateway |
| CT | GE HiSpeed Advantage | 3 | GE Dicom Gateway |
| CR | Fuji FCR 9000 | 5 | DASM → GE CRAW |
| | Fuji FCR 9501 | 1 | DASM → GE CRAW |
| | Fuji FCR AC1+ | 1 | DASM → GE CRAW |
| DSA | Philips V3000 + Easyvision | 1 | SMC Gateway → Merge Gateway → GE Dicom Gateway |
| | GE Advantx LCA | 1 | GE Dicom Gateway |
| | GE Advantx LCN | 1 | GE Dicom Gateway |
| DF | GE Advantx RNF | 1 | DeJarnette IM2000 → GE Dicom Gateway |
| | Shimadzu RSZ200 | 1 | Shimadzu IDR1000 → SMC Dicom Gateway → GE Dicom Gateway |
| | Shimadzu ZS40 | 1 | DASM → GE CRAW |
| | Shimadzu YSF220 | 1 | DASM → GE CRAW |
| US | ATL Ultramark 9 | 3 | SMC Dicom Gateway → GE Dicom Gateway |
| | ATL HDI3000 | 1 | SMC Dicom Gateway → GE Dicom Gateway |
| | Accuson 128 XP/10 | 3 | SMC Dicom Gateway → GE Dicom Gateway |
| | Accuson 128 XP/4 | 2 | SMC Dicom Gateway → GE Dicom Gateway |
| Film Scanner | Lumisys Lumiscan 220 | 2 | DASM → GE FDAW |
| Film Printer | Kodak 2180 | 3 | DASM → GE PCS |

**Table I: Imaging modalities interfaced to IMAC**

All 9 image acquisition units and 2 display workstations are based on MS Windows 95. One of the 9 US acquisition unit is a portable unit and the acquired images are stored on a 100 Mbytes removable media and later downloaded to the US imager server.

### 4.2 Image storage and database

The centralized data server works both as a large cache memory (256 Gbytes) and database for patient demographics and exams. The ISU 256 (GE, Mount Prospect, Il) image server is based on RAID level 3 and images are stored in 2:1 lossless compression effectively doubling on-line storage capacity. The host computer is Sun Sparc 20 Server and is integrated to the image data channel and database channel. There are two separate channels for image data and database text data. The relational database is Sybase 11 based on SQL. Attached to the main server is a backup server where a duplicate copy of the main database resides and this backup server is updated automatically with new transactions at every incremental tape backup.

Once the exams are acquired and sent to the ISU image server, the radiographers adjust the images for format, brightness, contrast and orientation. The exams are then queued automatically for archive onto a write-once-read-many (WORM) 15 Gbytes optical platter. 3 Kodak optical jukeboxes with a total of 4.5 Tbytes storage capacity are used for permanent archive. There are 3 separate archive controllers and each controller is able to write 4 exams and read an exam from two separate optical platters simultaneously. In addition to controlling the robotics of the jukebox, the archive controller also performs lossy/lossless

compression/decompression of images. CR images are 10:1 lossy compressed and MR/CT/US/RF/DSA are 2:1 lossless compressed before archived.

### 4.3 Operating Room IMAC

The workstation in all 23 operating rooms and 7 outpatient-surgery rooms access a separate image server (UniPACS, Samsung Data System). The host computer is Sun Enterprise 3000 with short-term storage of 40 Gbytes RAID. MS Windows NT based display workstations support 100MBps fast ethernet for both image and text data transfer. Scheduled exams are queried and retrieved from the main server (ISU) via a dicom query/retrieve dicom gateway based on the schedule-list queried from the hospital information system (HIS). Approximately 300-400 exams are transferred from ISU to the UniPACS server daily. The UniPACS supports both Korean and English text for demographic and exam information. Depending on the clinical need of the surgical rooms, either a dual monitor or single monitor workstations are installed. The main complaints of the surgeons, especially orthopedic surgeons, are: 1) not enough viewing screens (they would like to see several radiographs at full-screen view simultaneously, but due to lack of space in the operating room, providing more than 2 monitors was considered impractical); 2) inability to display the whole spine radiograph at full-size resolution; 3) in a brightly-lit operating room environment, the CRT display of images is not bright enough.

### 4.4 Allocation of workstations

Basically two different types of image display workstations are used: diagnostic and clinical image review. A diagnostic workstation has two or four monitors, 256-shade grayscale monochrome with resolution of 1535 by 2048. The luminance is set at 60 ft.Lamberts calibrated to the specifications recommended by the ACR-NEMA standards. A clinical workstation has one, two or four monitors, 256-shade grayscale monochrome, either landscape or portrait mode, with resolution of 1150 by 880 or 1024 by 1280. The luminance of the clinical workstations are set to 50 ft.Lamberts. All display workstations are based on Apple Macintosh, either PowerPC or Quadra. All together 186 display workstations are in clinical use and the locations are shown in Table II.

| Location of Workstations | W/S Manufacturer | Type | No. of Monitors | Monitor Manufacturer | W/S No. |
|---|---|---|---|---|---|
| Outpatient | GE | Clinical | 1 | Image System | 69 |
| | GE | Clinical | 2 | DataRay | 8 |
| Inpatient | GE | Clinical | 2 | Image System / DataRay | 36 |
| Radiology | GE | Diagnostic | 4 | MegaScan / Tektronics | 14 |
| | GE | Diagnostic | 2 | Image System | 1 |
| | GE | Clinical | 4 | DataRay | 3 |
| | GE | Clinical | 2 | DataRay | 7 |
| | GE | Clinical | 1 | Image System | 4 |
| | Apex | Clinical | 1 | Samsung | 2 |
| Referring Dept Conference Rm | GE | Clinical | 2 | Image System / DataRay | 10 |
| Auditorium | GE | Clinical | 1* | Barco (*Wall Beam Proj) | 1 |
| Conference Hall | GE | Clinical | 2* | ASK (*Wall Beam Proj) | 1 |
| Operating Rm | SDS | Clinical | 2 | DataRay | 7 |
| | SDS | Clinical | 1 | Samsung | 16 |
| Day Surgery | SDS | Clinical | 2 | DataRay | 1 |
| | SDS | Clinical | 1 | Samsung | 6 |

**Table II: Workstation types and location**

### 4.5 His to IMACS

Exam request orders are queried from the hospital information system by the HIS/IMAC gateway and sent to the main database server on IMAC. HIS/IMAC gateway uses the Health Level 7 (HL7) standard for message exchange between IMAC and HIS/RIS system. HL7 is a standard for transferring data and messages such as admission/discharge/transfer (ADT), order entry and result reporting among departmental systems that make up a HIS at a hospital. Once the radiologist digitally signs the final radiological reports, the IMACS database server sends the report to HIS also using the HL7 message exchange protocol.

### 4.6 Workload

In 1997 alone, the total number of exams acquired by IMAC was 512,516. CR exams accounted for 419,946, US exams for 38,832, CT exams for 21,430, MR exams for 16,197, DF exams for 10,239 and DSA for 5,872. The figures above do not include digitization of films brought from other hospital and input of historical exams from film. Currently, there are over 200,000 patients registered in the IMAC database server with over 8 million images.

The daily input volume to the main image server unit is approximately 12% of the total 256 Gbytes storage capacity and since 2:1 lossless compression is performed on all newly acquired images, this translates to approximately 61 Gbytes of daily input to the image server. In addition to the newly acquired exams, historical exams are fetched from the optical jukebox

and results in staggering number of exams residing in the image server. Once an exam is read by the radiologist and if there is no further display access to that exam then the exam is flushed from the image server based on first-in-first-out schema. A typical snapshot of the on-line and off-line status of newly acquired exams in the image server is shown in Figure 6. The rightmost bar is the most current day and all the acquired exams reside in the server typically in the process of reading by the radiologist. At fourth day, about 11% of the exams are flushed and at fifth day, about half of the exams remain in the short-term image server. Ideally newly acquired exams should remain in the short-term image server for at least 2 weeks (typical time interval between outpatient's revisit) before they are flushed. The capacity of the short-term storage at SMC needs to be increased to at least 1 Tbytes without compromising the performance of disk access time and display time of a typical image which is less than 2 seconds.

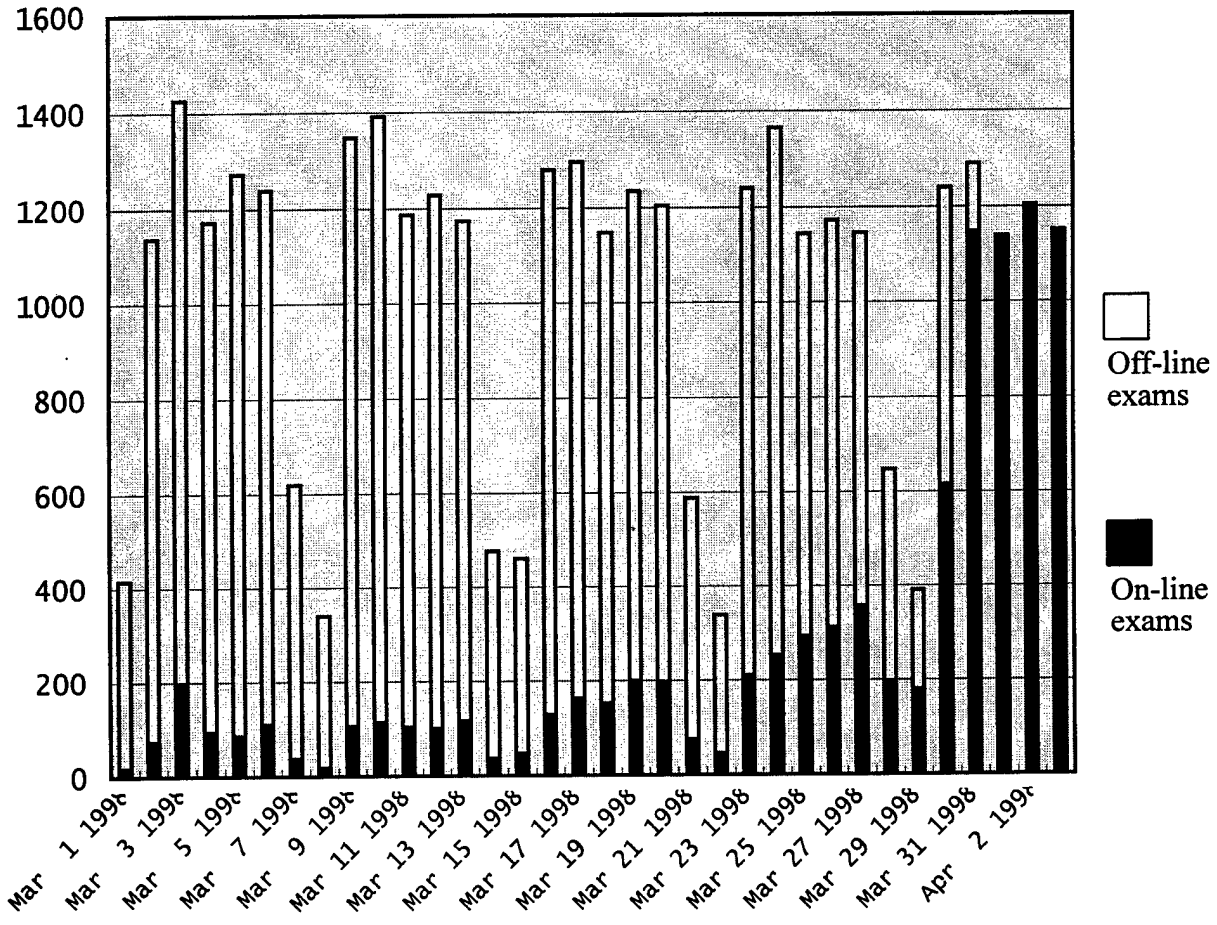


**Figure 6: Off-line and on-line exams residing on the image server**

## 4.7 Fetching historical exams

Two different types of fetching are in use for retrieving historical exams from the optical jukebox. The first is the automatic fetch when a new exam is ordered for a patient. For that particular exam, 4 historical exams are retrieved based on modality and exam procedure. For example, if a MR brain exam is ordered, then 3 most recent and 1 oldest MR brain exams are fetched automatically. The purpose is of course to have newly acquired exam with historical

exams available at the time of reading. The fetch starts as soon as a receptionist marks the exam request status as arrived. In most cases the time it takes for the patient to finish the radiological examination, and when radiologists start their reading sessions, the historical exams have been fetched and on-line. If the fetch (or retrieve) queue is empty, approximately 1 minute is required to fetch one CR exam. The second type of fetch is the manual ad-hoc fetch. On a daily basis, outpatient nurses fetch approximately 1,500 exams in preparation for the following day outpatients' visits. Also approximately 400-500 exams are requested for fetch by the clinicians for inpatients' exam reviews and research purposes.

## 5.0 Clinical Experience with a IMAC Network at Georgetown University

A general description of the progress of IMAC is presented here primarily based on the experience at Georgetown. While specifics may vary, it is suggested that our experience at Georgetown may be a reasonable representation of currently operational IMAC networks at various stages. There are a number of significant IMAC projects around the world where the experiences may differ at different stages of development. An example of such an undertaking was described in the previous section. Other examples are Hammersmith Hospital in London, Central Institute for Diagnostic Radiology of Donausital Solialmed of Vienna, Baltimore VA Hospital, and large military hospitals such Madigan Army Medical Center, Tripler Army Medical Center, Brooke Army Medical Center and Wilford Hall Medical Center has initiated a major effort to achieve a filmless radiology service. Many other facilities were able to reduce the dependency on film for diagnosis and image management. It is hoped that this analysis can provide a brief overview of the IMAC progress and present a general trend in IMAC activities.

### 5.1 Digital Radiography and Image Quality

Digital radiography can be obtained by using computed radiography (CR) or film digitizer. Images obtained by CR can be viewed on CRT monitors or printed on films using laser film printers. Therefore the acceptability of image quality must be qualified by the display method, CRT or film. In the past, workshop on digital radiography such as the one held in Mannheim, Germany [30] established a general consensus on the clinical acceptability of digital radiography. Current technology in printing CR images on film is comparable to the best that conventional film screen radiography can offer except in pediatrics and mammography. CR is the best system for intensive care unit bedside radiography in adults because it can produce images of consistent quality. In the past it was suggested that the radiation dose can be reduced by using CR systems, but this is not a generally accepted view any more. More work remains to be done in image processing for other applications, such as bone and extremities. When the digital images are displayed on high-resolution monitors, the CRT introduces additional variables in the image quality.

For film digitization, to produce a chest image of adequate quality for interpretation, the original film based image must be of appropriate quality for digitization. Tests have shown that with proper input quality, film digitization coupled with CRT display produces good quality images for IMAC. At Georgetown, we have routinely digitized chest images for transmission to one of our adult and one of our pediatric intensive care units. The clinical acceptance in our Adult ICU has been poor, however that in our Pediatric ICU has been high. The difference is probably due to the higher quality of the original film images in the Pediatric ICU. Tests of the images transmitted to the adult ICU have shown that because of the higher variability of quality of these images, these images have not always contained full information. When chest films were digitized at 2K x 2.5 K matrix and viewed on a high-resolution monitor (1K or greater) in an experimental environment, there was no statistical difference in the accuracy of diagnosis compared with the film. The system however is not used routinely for this purpose because the

user interface is poor for chest imaging.

One should note that the quality of images on film is optimized for direct viewing by the physicians. If the films are to be digitized the image quality must be optimized to match the optical characteristic of the digitizer. Some of the films today have a rather high contrast but for the digitizer a lower contrast may be more useful. More work remains to be done to optimize image quality of digitized films.

One type of difficulty in film digitization and workstation or database functions can be see in musculoskeletal images. Exams of the musculoskeletal system are the second most common examination performed at Georgetown with approximately 22,000 examinations per year. Our experience with IMAC in these cases has been limited to several experiments exhibiting the adequacy of image quality for most purposes and the problems resulting from the need for a specialized database for storage. Most cases acquired in musculoskeletal radiology are obtained on analog film systems. They are placed in the database for experimental purposes by film digitization. Many musculoskeletal images have poor original characteristics for film digitization because they are purposely obtained as high contrast analog images and there is increased noise present when blacker areas of an analog film are digitized. These blacker areas are the soft tissues surrounding the bone, and on digitized film images, the presence of joint effusions and soft tissue swelling sometimes can be difficult to detect. Furthermore, in our current database system, the inability to identify right or left limb is indeed a problem.

## 5.2 Performance of Workstations

Workstation performance gets the most attention in IMAC project, but one must realize that workstation performance depends on types of clinical uses, database design, quality of images that are placed on the network from the imaging systems, types of images, quality of CRT display, display speed and network performance, just to name a few.

If the workstations are to be used for review (after primary diagnosis), consultative or educational purposes, many of the performance requirements will be less demanding from that of primary diagnosis in a busy radiology service environment where image quality, display speed and system reliability requirements are highest. In general, most workstations are quite acceptable for reviews and educational activities, but few can meet the requirements for routine radiology services.

The database design requirements for radiological images have not been fully matured as of yet. Use of data compression, varying types of images, image descriptors, data distribution management and interface with other data systems such as radiology information system still present challenges to the system developers.

In the IMAC environment, images are optimized as the imaging systems and the image data are to be transmitted to the network through network interfaces. In the absence of digital interfaces or for images that are inherently analog, such as ultrasound images, analog-to-digital converters (ADC) are used. The use of ADC or frame grabber [31], as well as film digitizing degrade the image quality in terms of resolution, dynamic range and signal to noise ratio for the workstation. In general, assuming the images are digitally placed on the network, digital images such as MR and CT, compared with chest images, pose little difficulties for primary diagnosis on workstations. It is however important to be able to display many images (50-100 images of 256 x 256) on multiple displays for rapid global presentation.

Display of chest images on high-resolution monitors is more problematic. In a controlled

environment with a multi-screen workstation, experimental users find that the diagnostic accuracy on CRT reading is statistically equivalent to that of films. The chest images must have at least 2K x 2.5K matrix size with minimum 10 bits of data. Only recently, a small number of institutions have been able to use workstations for primary diagnosis rather than films. The most common complaints about workstations have been display speed and clumsy user interfaces that limit overall throughput.

### 5.3 Teleradiology

The ISIS Center of the Department of Radiology at Georgetown recently collaborated with the U.S. Army in developing an off-the-shelf teleradiology network for Operation Joint Endeavor, the peace-keeping mission in Bosnia. The network shown in Figure 7 is part of Operation Primetime III, a project to deploy advanced communications and medical equipment to provide state-of-the-art medical care to the 20,000 U.S. troops stationed there. The network encompasses three major sites: the 212th Mobile Army Surgical Hospital (MASH) in Tuzla, Bosnia; the 67th Combat Support Hospital (CSH) in Taszar, Hungary; and the Landstuhl Regional Medical Center (LRMC) in Landstuhl, Germany.

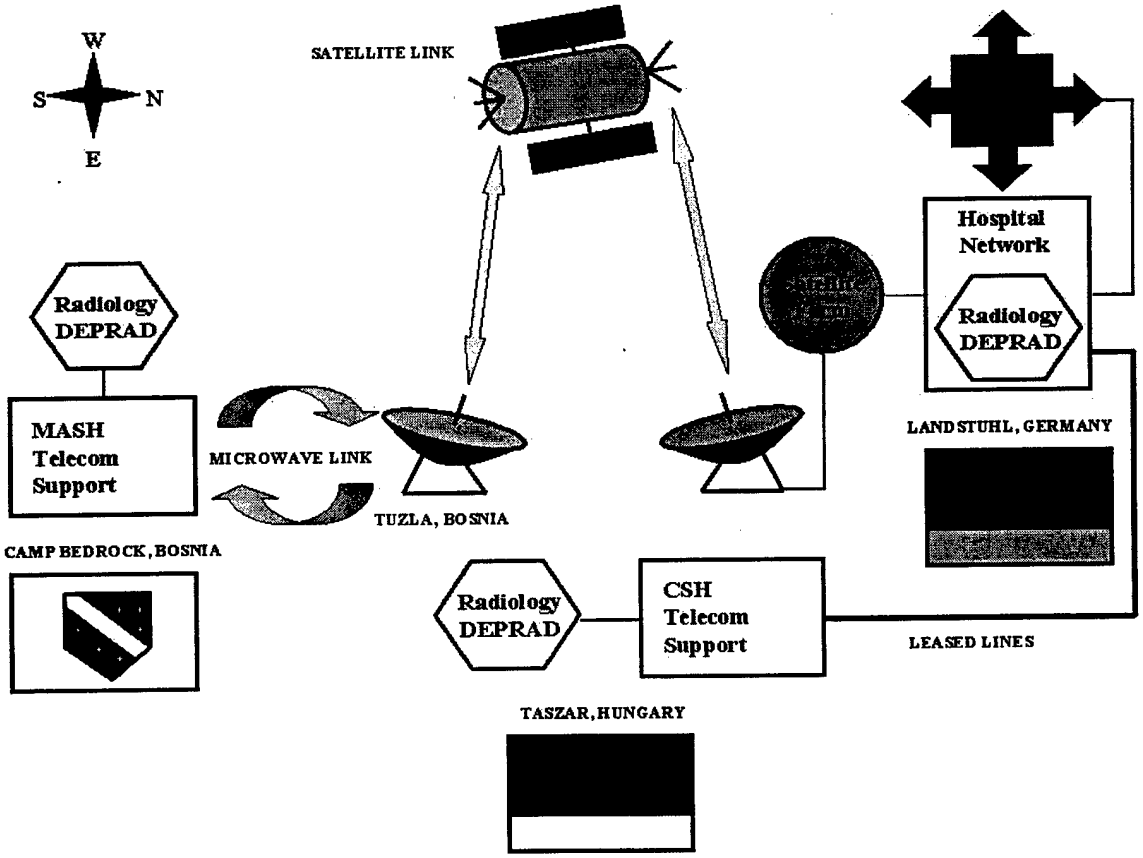


**Figure 7: Deployable radiology (DEPRAD) imaging network for Bosnia**

At the MASH in Bosnia, a radiology local area network has been installed which supports the following three modalities plus film digitization: CR, CT, and US. There is softcopy display and hardcopy output provided as well. The CSH configuration is quite similar. The LRMC

installation was designed to receive images only from the MASH and CSH and display or print them as necessary. The clinical scenario is to acquire images using any of the three modalities listed above or by digitizing existing film. The images are then sent over a local area network to a diagnostic display workstation in the radiology area for storage and viewing. Since there is typically not a radiologist at the MASH, the images are then transmitted to the CSH for primary diagnosis and archiving. Images can also be transferred to other display stations within the MASH depending on the patient location (EMT, ICU). Operations at the CSH are very similar to the MASH; however, the CSH usually receives more images than it transmits.

## 5.4 DICOM

Since the publication of the first version of the ACR-NEMA Version 1.0 standard in 1985, a revision in 1988 to become ACR-NEMA Version 2.0 and the most recent major publication of version 3.0, also popularly known as DICOM [25], the medical imaging industry has widely adopted the standard to allow exchange of digital information (images) between medical devices (modality/workstation/IMAC). Key features of DICOM include:

(a) Transfer of digital images from imaging modalities such as MR, CT, CR, US, NM, captured images, image overlays and lookup tables.
(b) Selectively query and retrieve imaging studies of patients.
(c) Direct connection of medical equipment to standard TCP/IP network environment without an intermediate network interface, and the integration of imaging equipment with hospital information systems.
(d) Framework for claiming conformance to DICOM so that manufacturer of a product can specify explicitly the implemented function of the DICOM standard.

DICOM is an evolving standard that not only deals with the activities of radiology but also encompasses other clinical domains. For example addressing the needs of the cardiologists to find a digital replacement for cine film for cardiac angiography, new information objects were added to DICOM to support angiography and to standardize interchange media on recordable compact disk (CD-R). Currently clinical groups such as the College of American Pathologists (CAP), the American Society of Gastrointestinal Endoscopists (ASGE), the American Dental Association (ADA), the American Academy of Ophthalmologists (AAO) are participants in the development of the standard. Harmonization activities with other standard development organizations such as HL7 and CORBAMed are in progress to standardize exchange of information across hospital-wide and enterprise-wide network.

## 5.5 Next generation of IMAC: internet

> "One of the most important aspects of the Next Generation Internet (NGI) in the health sciences is the use of computer and telecommunication technology for medical diagnosis and patient care - what has come to be called telemedicine." *Dr. Donald A.B. Lindberg, Director, National Library of Medicine, in statement to the House Appropriations Sub-Committee on Labor, HHS, and Education, March 18, 1998.*

The need for distributed and architecture-neutral medical information systems will increase with health care reform. Existing medical information systems are inadequate in dealing with sharing of electronic medical records and applications across heterogeneous platforms. To

accelerate the integration of emerging information technology into the medical informatics infrastructure, a number of initiatives under the auspices of National Library of Medicine, a component of the Department of Health and Human Services' National Institutes of Health, are underway to develop: testbed networks to link hospitals, clinics, medical schools and libraries to allow for sharing of medical data and images; collaborative technology for real-time treatment of patients; information access; and virtual reality for medicine Web/Java programming [32]. The focus is to build internet-accessible shared systems tying together major hospitals with community clinics and pharmacies, providing access to a computerized patient records, computerized prescriptions, teleconferencing and online medical knowledge sources.

With such development of internet-based IMAC, the patient privacy and security of medical information is emerging as a significant concern. Network security should be maintained to prevent interception of messages by a third party in the middle of two connection ends. Also end-point security must not be compromised to allow unauthorized client to access restricted host or database. Data encryption, data integrity and server authentication methods used in the world-wide-web (www) technology for secure data exchange may be further developed to protect patient's privacy and confidentiality of data security

## 6.0 Conclusion and Future Activities

An information management project such as IMAC brings out many deficiencies in the current system. Many of these old shortcomings which may not be directly related to imaging must be addressed to take full advantage of communication and management technologies. Past experience suggests that for long term success the entire process of radiology operations including communication and management infrastructure must be addressed so that one of two bottlenecks do not bring down the entire network and limit the utility of the new capabilities.

Seen from the patient care and hospital operational perspective IMAC technology together with imaging technology must offer clear advantages for the radiology service in three general areas; (a) new digital imaging modalities to reduce the dependence on film, (b) significant operational improvements and (c) new diagnostic information.

The introduction of CR technology has been a significant factor in IMAC, and more manufacturers are offering competitive capabilities. While it is clear that current technology can replace most of the film imaging for chest and bone, new higher resolution capabilities may be required for hands and premature infants. A number of new x-ray detectors have been studied to develop new digital radiography systems. Mammography is an important part of radiology service, but a digital mammography system is yet to be developed. A great deal of activities are underway to develop a digital mammography system [33] that requires much higher resolution (50 micro per pixel) than chest imaging.

Operationally, image database is a subset of radiology information system (RIS). Integration of IMAC network to RIS is an essential part of IMAC technology. Collaboration between IMAC developer and RIS/HIS developers is needed in the future. As discussed earlier the imaging system of the future must have more efficient and less costly interface capabilities based on a common standard.

In the past some of us viewed IMAC as a means to move images rapidly, but as image processing capabilities become faster and less expensive, IMAC should be more than an image management system. The network should provide additional capabilities that can improve the quality of diagnosis. This can be achieved by integration of computer-aided diagnosis, tissue characterization, 3-dimensional image display and multimedia data presentation.

Two types of changes [34] that will result from new information management technology such as IMAC; changes in work habits and changes in power and control. The changes in work habits will involve changes in the location and techniques used for viewing images and in the manner in which the radiologist provides radiology consultations. Fewer will be in the x-ray department, more will involve phone consultations with both parties looking at the image simultaneously.

Everyone in patient care recognizes the problems faced by radiology services, especially in film and report management, but it is difficult to agree on which party should address the problems. With the current file system, the images are controlled by the radiology department and the problems related to them are the responsibility of the radiologist and radiology administrator; there is power in having that control. With IMAC, the images are available throughout the hospital, and therefore the power that comes from control is decreased. Radiologists will be losing some of their control over the images. In order to maintain their effective consultative relationship and their ability to bill for services they will have to work smarter so that the reports are available with the images.

In most cases, an IMAC system does not develop new sources of revenue. One of the major challenges for any hospital considering an IMAC is justifying its financing. If a technology does not result in new income, then its costs must be justified by cost savings either of supplies or in personnel. If one does not create a film image, then there are substantial savings to be made in not using film, film jackets and developer. At Georgetown, the annual film costs are close to $700,000. While it may be possible to decrease the number of film librarians after a transition period, it is likely that IMAC will result in new tasks for an equivalent number of workers. The major personnel saving that can result from an IMAC is in its saving physician time, mainly the time of the primary physician and clinical consultants.

While the clinical acceptance of IMAC technology has been spotty in the past, a growing number of projects using newer technologies have increased clinical acceptance. As more competing products are introduced in all areas of IMAC technology, integration of radiology imaging systems will take place in various forms to improve overall efficiency of radiology service. IMAC technology is a special case of network computing which has become common in other areas. For existing hospitals, it will take some time to modify all radiological imaging systems to be network compatible. Currently, manufacturers of imaging systems cannot remain competitive without providing their equipment with DICOM connectivity capabilities for IMAC network.

A hospital cannot perform its mission of delivering timely and efficient health care without the collection and distribution of a mass of diagnostic, treatment, and management information. As the number of diagnostic and therapeutic procedures have increased, the information management requirements placed on hospitals by government and insurance industry have grown. Furthermore, as patient awareness of health issues has blossomed, hospital departments have turned from largely manual methods to computer based systems of many types. In general, though,

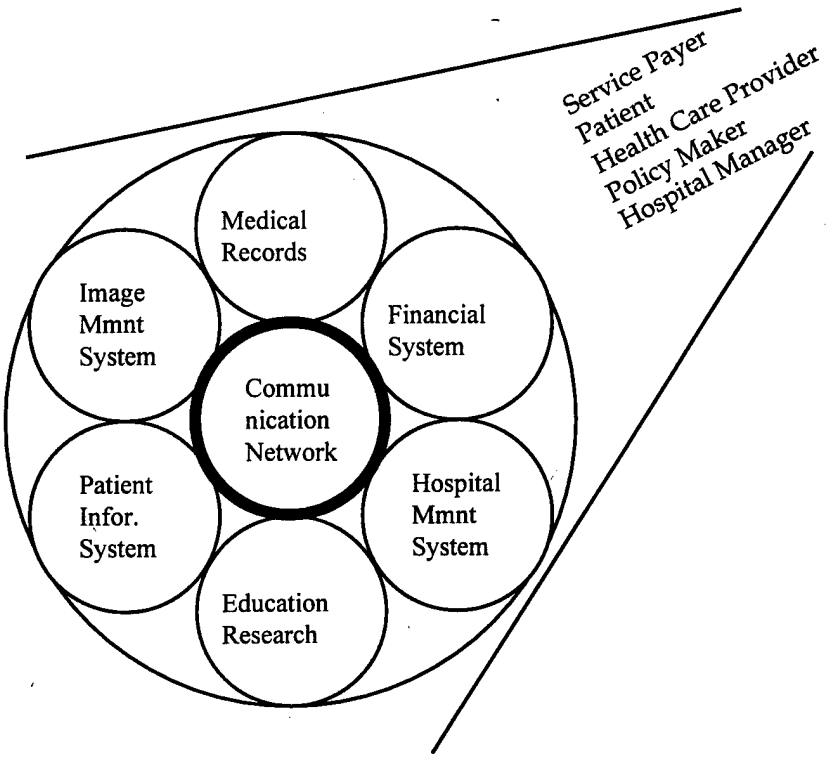


**Figure 8: Fully integrated hospital information system**

the attitude about such systems has been somewhat self-centered in that each department or division tends to develop a system to solve its own problem as a primary goal with the concern of other areas considered secondary.

A fully integrated hospital information system, as depicted in Figure 8, will be able to

(a) Optimize the resource utilization
(b) Lower communication costs
(c) Improve quality of care
(d) Minimize operational dependence on paper and film
(e) Facilitate effective research and education support.

Furthermore, various health care providers and patients will be able to gain a better understanding of the operations of the hospital as a whole. A fully integrated system as depicted here is not yet a reality, but that must be the goal for all communication and management information systems required to run a hospital. Challenges are numerous but we are closer than ever to reaching our goal of film independent imaging service throughout the hospital. Similar challenges have been met in other industries [34, 35] when a prudent management deployed computerized information management system matching the technical capability to the carefully targeted problem areas.

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# Chapter 7

## Computerized Patient Record Tool Kit

Computer-based patient record systems (CPRS) may potentially achieve greater protection of health information than paper-based records. Ensuring an appropriate and consistent level of information security for computer-based patient records, both within individual health care organizations and throughout the entire health care delivery system, requires organizations entrusted with health care information to establish formal information security programs. Recognizing the importance of information security in managing computer-based patient records, the Computer-based Patient Record Institute (CPRI) chartered the Work Group on Confidentiality, Privacy, and Security to promote this process. Since its inauguration in 1993, the Work Group has developed and published a series of topical guidelines on improving information security for organizations implementing CPRS.

The guideline series addresses individual issues in information security, but, taken as a whole, promotes a comprehensive organizational process. The CPRI believes that managing health care information requires integrating good security processes into the everyday working routines of all staff, not just implementing security measures. Toward that end, the CPRI charged the Work Group to consolidate its guideline series into a toolkit that outlines general principles and provides "best practice" examples of how health care providers should manage the security of their paper and electronic records. The sections of the CPRI Toolkit identify key activities that health care providers should initiate as part of managing information security, including:

Monitoring and adjusting to the changing laws, regulations, and standards
Developing, implementing, and continuously updating data security policies, procedures, and practices
Enhancing patient understanding of the organization's information security efforts
Institutionalizing responsibility for information security

Each section includes an introduction, a copy of the latest edition of the pertinent CPRI guideline, several case studies with sample policies, procedures and forms, and extensive references to print and Internet sources of more information. A consolidated annotated bibliography, a list of Web sites, and a glossary of terms appear at the end of the CPRI Toolkit. With this toolkit, any health care provider should be able to plan, implement, and evaluate a security surveillance process scaled to their organizational needs.

The legal, social, and technical environment surrounding CPRS will remain dynamic, thus requiring all health care providers to be vigilant in the years to come. The CPRI has designed this toolkit to assist health care providers in adapting to the changing circumstances affecting management of information security. The CPRI Toolkit contains examples of "best practices,"." but health care providers should consult with their legal departments and assess their own situations before adopting any forms, policies, or procedures contained in the CPRI Toolkit.

**How to Use the CPRI Toolkit**

Healthcare organizations will find valuable resources in the *CPRI Toolkit* to assist in managing the security of business, clinical and other types of health information, particularly in computer-based record systems. The *CPRI Toolkit* includes guiding principles, case studies and paradigmatic examples of how to build a health information security program, including "hot links" over the World Wide Web to important sites. New regulations on the security of computer-based health information promulgated by the Department of Health and Human Services subsequent to the Health Insurance Portability and Accountability Act of 1996 make accomplishing this task salient and necessary for all healthcare providers, payers and clearinghouses. In order to keep faith with and maintain the trust of patients, clinical and business partners and the general public, nonetheless, healthcare organizations should seek capably to assure the confidentiality, integrity and secure accessibility of their information as a matter of basic business practice. Assuring information security has the reputation of being a highly esoteric technical enterprise. The *CPRI Toolkit* makes the case that maintaining information security should be an aspect of the everyday work of all members of the organization (including its customers), not just of "security specialists" or information technologists alone. The *CPRI Toolkit* offers guidance in accomplishing three basic security program functions, namely:

1) Monitoring changing laws, rules and regulations;
2) Updating information security policies, procedures and practices, and;
3) Enhancing patient understanding and acceptance.

By accomplishing these functions healthcare organizations potentially institutionalize a sense of responsibility for information security throughout their operations thus building the foundations of a competent, defensible information assurance program.

To take best advantage of the resources contained in the *CPRI Toolkit*, healthcare organizations should develop and sustain a security surveillance process that typically includes the following critical steps:

1) Assigning responsibility for managing information security;
2) Developing and implementing a plan for managing risks to the confidentiality, integrity and secure accessibility of an organization's information;
3) Measuring and documenting the impact of administrative and technical countermeasures taken in execution of the information security plan, and;
4) Reevaluating and adapting the plan in light of experience.

As implied by the feedback loop linking experience to the original plan, the security surveillance process never ends but should occur as part of a healthcare organization's regular administrative operations. Such a broad-based, recurrent approach will build administrative support for and enterprise-wide awareness of the importance of information assurance – both of which will be necessary to meet the deadline for implementation of the HIPAA security regulations in early 2002. This approach also shares with the HIPAA regulations a strategy of health information security based on risk management, not risk avoidance. It thereby should help healthcare organizations comply with HIPAA as it enhances their overall competence in health information assurance.

The organization of the *CPRI Toolkit* encourages healthcare organizations to keep their eyes focused on three broad security functions: monitoring their federal, state and professional regulatory and legal environment, updating their own internal environment of policies, procedures and practices, and communicating with their patients. As healthcare organizations work their way through the critical steps of the security surveillance process, they will find resources in the *CPRI Toolkit* linking the process to these three broad functions. The resources come in several forms.

1) Monitoring Laws, Regulations and Standards: Chapter 3 devotes great attention to the extensive HIPAA-provoked federal activity in health information security and provides extensive materials about state and professional activities in health information assurance. This chapter includes summaries of all the HIPAA electronic transaction and data security regulations and of the Notice of Proposed Rulemaking on medical privacy. A special matrix creates "hot links" between the HIPPA requirements and pertinent sections of the *CPRI Toolkit.* A section on state law includes information on how to investigate legislative action in all fifty states as well as a recent evaluation of the state scene prepared by the Georgetown University Health Privacy Project. The Executive Summary of the JCAHO/NCQA Recommendations for Protecting Personal Health Information is republished with permission in recognition of the central role of these two accrediting bodies for healthcare providers. Finally, DHHS and professional information security specialists regularly refer to and depend upon the work of a range of standards setting organizations, a realm that often remains somewhat obscure to many healthcare professionals. In order to demystify and recognize the importance of standards setting organizations, the editors of *CPRI Toolkit* asked Margaret Amatayakul, former executive director of the CPRI, to write an introduction to setting standards in health care information. Using the resources in this section of the *CPRI Toolkit*, any healthcare organization ought to be able to discover and track the various federal, state, and professional requirements in health information security and privacy to which they must comply. HIPAA gives this section special salience now; but, monitoring laws, regulations and standards for healthcare constitutes work that never ends for healthcare organizations in this and all aspects of their operation.

2) Updating health information policies, procedures and practices: Since its inception in 1993, the CPRI Work Group on Confidentiality, Privacy and Security has published booklets on specific topics in health information security. Each booklet is reprinted in Chapter 4 accompanied

by samples and case studies illustrating the critical steps healthcare organizations should take to plan and implement a health information security program. Sample security policies illustrate how eight different healthcare organizations of varying scale have addressed the issues discussed in "CPRI Guidelines for Information Security Policies." Section 4.5 contains an introduction to information security risk assessment and a case study on telemedicine from Georgetown University Medical Center. To learn about "Assigning Roles and Responsibilities" in health information security, consult section 4.4 with the reprinted "CPRI Guidelines for Managing Information Security Programs" and a case study from the University of Pennsylvania. A comprehensive information security training course complete with "Instructor's Guide", all necessary slides, and pre and posttests accompanies the "CPRI Guide to Information Security Training". Information about organizations that sponsor regular training in information security training and references to other resources complete the section. To learn about how organizations enforce security policies, consult section 4.8, which contains sample confidentiality statements/agreements and a case study on securing user agreement at Kaiser Permanente Northern California. A special section focuses on issues in the electronic transmission of health information such as email, fax and the Internet. HCFA's new Internet Policy appears accompanied by a discussion of PCASSO, an NLM-sponsored project giving patients and providers secure remote access to computer-based patient records at the University of California San Diego Medical Center. This includes discussion of certain information security technologies such as firewalls and encryption.

3) Enhancing patient understanding of an organization's health information security program. In the new millennium, patients will hold healthcare organizations accountable for many aspects of their business practice as well as medical care. As this second edition of the *CPRI Toolkit* goes to press, Congress is debating Patients' Bill of Right legislation to permit suit of managed care companies for denial of service and other business practices. Such bills and supporting anecdotes provide some evidence of public dissatisfaction with the consequences of reforms in healthcare finance during the last decade. Demands for greater accountability in the use of personally identifiable health information reflect distrust of complex organizations and their power over the lives of individuals. The DHHS suggests that federal medical privacy laws or regulations include requiring healthcare organizations to give patients the right to review and propose corrections to their medical record as well as document and permit patients to review lists of disclosures. Chapter 5 of the *CPRI Toolkit* includes procedures and forms from AHIMA illustrating how healthcare organizations might responsibly provide these services. Healthcare providers might actually go one step farther and use the public's concern about medical security and privacy to build trust. Chapter 5 includes a discussion of "HelpBot", Georgetown University Medical Center's web-based explanation of its efforts to assure the confidentiality, integrity and secure accessibility of

patient information in telemedicine. Instructions for tailoring "HelpBot" to an organization's own needs are included.

Institutionalizing sound security practices requires creating sustaining structures at all levels of the organization. Security seminars routinely repeat two basic truisms: 1) the CEO should publicly support an organization's information security program, and 2) confidentiality is everybody's business. Questions about how to integrate information security into an organization's life less frequently get posed. Of particular concern is the tendency to isolate information security from clinical and business operations. Through an arrangement called "Trustee-Custodian Agreements" Kaiser Permanente has developed a means of tightly sharing responsibility for information security between information specialists and clinical and business users. Chapter 6 includes a detailed discussion of the process and sample agreement forms.

The *CPRI Toolkit* offers a gateway into thinking about managing information security in healthcare. Because this second edition exists "on the web" as well as on paper, it literally functions as a means of finding resources beyond its own boundaries. To assist users in this task, Chapter 7 lists all the addresses of references to sites and information on the World Wide Web with activated "hot links". Chapter 8 includes a glossary of terms updated from the previously published CPRI "Glossary" and a web link to the HIPAA glossary. Chapter 9 lists important references in the field of health information security.

The *CPRI Toolkit* does not contain recipes for compliance with HIPAA or a foolproof security system. Like the very best cookbooks, however, it includes extensive review of policies (what is wanted), procedures (how to do what is wanted) and practices (what actually gets done) which, when thoughtfully deployed, give evidence of due diligence and yield an administratively disciplined, defensible program. Nor will technology alone yield a responsible program. Each healthcare organization must blend technology with policies, procedures and practices to create a mix consistent with its own mission and business philosophy. Information security management in healthcare as elsewhere requires managing risks that cannot be avoided as long as one remains in business. Managing risks requires exercising administrative judgement. The editors of the *CPRI Toolkit* hope that this document will enhance the ability of all healthcare professionals to exercise competent administrative judgement as we work to better the health of our patients, enrich the working lives of our staff and protect our organizations.

Computer-based patient record systems (CPRS) may potentially achieve greater protection of health information than paper-based records. Ensuring an appropriate and consistent level of information security for computer-based patient records, both within individual health care organizations and throughout the entire health care delivery system, requires organizations entrusted with health care information to establish formal information security programs. Recognizing the importance of information security in managing computer-based patient records, the Computer-based Patient Record Institute (CPRI) chartered the Work Group on Confidentiality, Privacy, and Security to promote this process. Since its inauguration in 1993, the Work Group has developed and

published a series of topical guidelines on improving information security for organizations implementing CPRS.

The guideline series addresses individual issues in information security, but, taken as a whole, promotes a comprehensive organizational process. The CPRI believes that managing health care information requires integrating good security processes into the everyday working routines of all staff, not just implementing security measures. Toward that end, the CPRI created a new Task Force to consolidate its guideline series into a toolkit that outlines general principles and provides "best practice" examples of how health care providers should manage the security of their paper and electronic records. The sections of the *CPRI Toolkit* identify key activities that health care providers should initiate as part of managing information security, including:

- Monitoring and adjusting to the changing laws, regulations, and standards
- Developing, implementing, and continuously updating data security policies, procedures, and practices
- Enhancing patient understanding of the organization's information security efforts
- Institutionalizing responsibility for information security

Each section includes an introduction, a copy of the latest edition of the pertinent CPRI guideline, several case studies with sample policies, procedures and forms, and extensive references to print and Internet sources of more information. A consolidated annotated bibliography, a list of Web sites, and a glossary of terms appear at the end of the *CPRI Toolkit*. With this toolkit, any health care provider should be able to plan, implement, and evaluate a security surveillance process scaled to their organizational needs. These resources should aid healthcare organizations in securely managing information, particularly as they develop responses to new federal regulations and laws such as HIPAA.

**Monitoring Changing Laws, Regulations, and Standards**

Currently, questions of health information security and medical privacy are of utmost importance in the United States. Hardly a day goes by that *The Washington Post*, *The New York Times*, or *USA Today* do not feature an article about some aspect of medical privacy. Opinion polls document that the American public regards the data management practices of most large organizations with great skepticism. In partial response to these and other expressions of public concern, President Clinton commissioned a task force on medical privacy as part of his health care reform efforts. Although the recommendations of the privacy task force died along with Clinton's plan, federal legislators have incorporated some of their intent, particularly the requirement of federal medical privacy legislation, into subsequent approaches to health care reform. . The Health Insurance Portability and Accountability Act of 1996 (HIPAA))creates specific requirements for the Congress and the Department of Health and Human Services (DHHS). Because of HIPAA, the legal and regulatory environment for managing patient medical records has dramatically changed. DHHA has developed regulations for managing health information security (see below Chapter Three). Efforts

to develop federal medical privacy requirements continue in both Congress and DHHS. DHHS led the way on medical privacy by designing model rules to guide Congress and/or its own process of rulemaking if necessary. Meanwhile, many standards-setting organizations are busy addressing the problems of medical privacy and the security of health care information from their own perspectives.

The *CPRI Toolkit* contains summaries of the DHHS rules, the DHHS model medical privacy provisions, information about tracking state laws on medical privacy, and a thorough explanation of the standards-setting process in medical informatics. As an example of how two important standards-setting organizations in health care, the Joint Commission on the Accreditation of Healthcare Organizations and the National Committee on Quality Assurance, are beginning to incorporate demands for adequate data security practices into their evaluation criteria, a copy of the Executive Summary of *Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment* can be found in chapter three of the *CPRI Toolkit*.

**Developing Policies, Procedures, and Practices for Information Security**

Changes in the regulatory and legal environments, the security risks of distributed networks and systems, ever-changing information technology, and rising patient expectations all require health care organizations to continuously update their data security policies, procedures, and practices. A security team must take primary responsibility for coordinating this effort through careful risk analysis, security policy review, and technical and operational enhancements. The security team's efforts will fail, however, without strong business and clinical leadership from throughout the organization. Even if key leaders accept responsibility for maintaining the confidentiality of patient identifiable information, staff will probably resist taking on new tasks that further complicate their work and compete with current tasks. The security team must recognize that enhancing the organization's security capability requires transforming institutional resistance into a mission-based mobilized security effort. A security team that neglects building support for its efforts risks failure.

Included in the *CPRI Toolkit* are sample documents illustrating approaches to security policies, security risk analyses, patient consent and disclosure documents, and other issues from several organizations including the American Health Information and Management Association, Kaiser Permanente of Northern California, Partner HealthCare System, Inc., Harvard Vanguard Medical Associates, and several NLM-funded sites. These examples should assist any health care program, large or small, in its efforts to enhance the security of its confidential information.

**Enhancing Patient Understanding of Information Security Efforts**

As the DHHS recommendations on confidentiality make clear, health care providers face new obligations in informing patients about how they manage health information. The DHHS recommendations signal some broad social changes, however, whose significance transcends the narrow legal and regulatory context of their

development. Reforms in health care finance (specifically the emergence of managed care) are refocusing some aspects of health care from the doctor-patient relationship to the organization-patient relationship, thus making health care organizations accountable to patients in new ways. In addition to being accountable for health care processes and outcomes, organizations are becoming accountable to patients for their business practices, particularly for what they do with information about their individual cases. These changes, as well as DHHS proposals, will increasingly require health care organizations to obtain new types of consent, provide patients access to information historically reserved for institutional use only, educate patients about their business practices, and extend new services to their patients using electronic media. Patients are also demanding a variety of Internet and web-based healthcare services, including email and access to their medical records. Model examples for how some health care organizations are trying to meet these new obligations are included in the *CPRI Toolkit*.

**Institutionalizing Responsibility for Information Security**

The well known maxim "Confidentiality is everybody's business" states the basic truth. Transforming this truism into practice requires institutional work and personal commitment. This toolkit provides models and methods for assisting health care providers to manage patient records as a broad institutional process, including the technical protection of the information system. In addition to these concrete methods, however, health care providers should institutionalize a sense of responsibility for maintaining patient confidentiality at all levels, including individual staff, program managers, and organizational administrators. Health care providers should develop methods for binding these levels of responsibility together such as in the illustration of the "Trustee/Custodian Agreements" from Kaiser Permanente explained in the final section of the *CPRI Toolkit*. By creating the trustee/custodian relationship, Kaiser has institutionalized mutual responsibility for secure information control between clinical and information staff, thus integrating it not segregating it from everyday work. Not all health care providers require developing an arrangement as formal as Kaiser's Trustee/Custodian Agreement. Yet, most organizations larger than a single physician office differentiate between clinical and information systems staff. Formulating roles institutionalizing a sense of mutual responsibility for information security among staff operationalizes the idea that confidentiality is everybody's business. Instead of relegating information security to the domain of the technical specialists and parceling responsibility for managing patients only to clinicians, all staff assumes responsibility for the enterprise, its patients, and the confidentiality of their information.

# Chapter 8

## Technical requirements for image-guided spine procedures workshop questionnaire summary

Dramatic advances have been made in image-guided procedures in the brain over the past few years but relatively little attention has been given to other regions of the body such as the spine. A workshop titled "Technical Requirements for Image-Guided Spine Procedures" was conducted 17-20 April 1999 that reviewed the barriers to progress in this field and identified the technical and professional developments required to move ahead. The general objective of the workshop was to determine the technical requirements for image-guided procedures in the spinal column, spinal cord, and paraspinal region. Before the workshop, a questionnaire was sent to all the participants asking them to identify barriers to progress and areas for future research. The questionnaire results are presented in this paper.

### 1.0 Questionnaire Overview

The questionnaire was sent to all the workshop participants some four months before the workshop. The questionnaire had three major sections: 1) system-level questions, 2) clinical questions, and 3) working group questions. The working group questions were divided by the six working groups: 1) operative planning and surgical simulators, 2) intraprocedure imaging and endoscopy, 3) registration and segmentation, 4) anatomic and physiological modeling, 5) surgical instrumentation, tooling, and robotics, and 6) systems architecture, integration, and user interfaces. As of this writing (March 1999), 28 questionnaires had been returned. The questions and a summary of the responses are presented here.

### 2.0 System-Level Questions and Responses

1. What are the major technical problems and research needs in image-guided procedures of the spine?
2. What are the major infrastructure and administrative issues that must be addressed to move ahead with image-guided spine procedures?
3. What piece of technology or technological advance do you wish you had today?
4. What will be possible over the next 5 years? Over the next 10 years?

As for the major technical problems and research needs, image registration was the most common response. Registration is a fundamental problem of image-guided surgery, and commercial image-guided surgery systems require a step in which pre-procedure images are registered to the patient. For the spine, registration methods need to be developed that can account for the multi-body nature of the problem. Registration is also discussed in Section 4.3 in this paper in the registration and segmentation working group.

Several respondents mentioned the need for real-time imaging, particularly three-dimensional (3D) imaging such as CT or MRI. The issue of system integration and the need to develop a system tailored to the needs of spine surgery was also mentioned. The user interface for such a system needs to be developed so that information is presented to the doctor without interfering with the performance of other tasks.

Major infrastructure and administrative concerns include the coordination of clinical and technical personnel, the need to show the cost effectiveness of new technology, and a focus on solving clinical problems. Several respondents noted that engineers need to be more aware of clinical needs while other respondents said that physicians need to be more aware of what the technology can do and participate more in the design of technology solutions.

The desired technological advances were varied and included advances such as realistic and computationally efficient soft-tissue models, specific case simulation capability, real-time tissue segmentation and volume rendering, and improved image fusion tools.

Predicting the future is always a risky business, but several respondents believe that robotic systems for certain tasks will become more common over the next 5 years. Other respondents predicted progress in imaging modalities, including further development of CT-fluoroscopy and real-time MRI guidance. Over the next 10 years, the further development of the underlying technologies is anticipated, with one respondent suggesting that image-guided minimally invasive procedures would begin to dominate the operating room.

## 3.0 Clinical Questions and Responses

1. What 3 to 5 spine procedures do you most commonly perform?
2. In what 3 to 5 spine applications will image-guided procedures be widely used in the next decade? When will they be introduced (1-2 years, 3-5 years, 5-10 years)?
3. What are the major difficulties in introducing image-guided procedures? What would you like to be able to do in the spine that you cannot do right now?
4. What are the most time consuming aspects of spine procedures?
5. What are the 5 most common complications in spine procedures?

It should be noted that there were only seven respondents to the clinical questions. The most commonly cited spine procedures were discectomies and fusions, while several respondents also mentioned tumor resection. Other procedures included pedicle screw placement, C1-2 transarticular screw placement, lumbar cage placement, vertebroplasty, osteotomy for deformity, discography, and sympathectomies. Many of the procedures require the placement of hardware and others require directing an instrument to a precise spot percutaneously. Image guidance in one form or another is essential in both of these cases.

Applications where respondents believed image-guided procedures would be widely used in the next decade included existing applications such as pedicle screw placement and new applications such as deformity surgery. Other applications cited were tumor resection, spinal endoscopy, and the placement of interbody devices such as cages. One respondent noted that image-guided procedures are already widely used in the spine at some institutions.

Both technical and administrative issues were seen as the major difficulties in introducing image-guided procedures. On the technical side, image-guided systems need to be both accurate and easy to set-up. The registration process is still seen as difficult and cumbersome by many clinicians. On the administrative side, the turf battle between specialties needs to end, FDA approval is seen as a stumbling block, and reimbursement codes for image-guided procedures need to be expanded.

The responses to what physicians would like to do in the spine that they cannot do right now include guide pedicle screw placement, visualize margins of tumors, percutaneous spine fusions, multi-segment tracking, and laminoplasty.

The most time consuming aspects of spine procedures were noted as procedure dependent. Responses included taking off the bone in decompressive procedures, taking out the tumor in tumor resection, getting the exposure needed in complex cases, neurological decompression, scar removal, and nucleotomies in special imaging.

In response to the most common complications, the importance of proper patient selection was stressed. Complications included infection, neural damage, bleeding, failed fusion, and spondylodiscitis.

## 4.0 Working Groups Questions and Responses

As noted in the Overview, there were six working groups. Each working group had a clinical co-chair and a technical co-chair. In the questionnaire, the participants were asked to list their top three choices for a working group, and each participant was asked to respond to as many questions as they felt comfortable with. In this section, a brief description of each working group is given followed by the questionnaire responses to the first three questions given below. The responses to question 4 concerning spine procedures are given across all working groups in Section 5, Spine Procedures. The questions were the same for each working group, except the name of the working group was changed. As an example, the questions for the operative planning and surgical simulators group were:

1. What are the major technical problems with operative planning and surgical simulators?
2. What other factors are limiting the use of operative planning and surgical simulators?
3. On a scale of 1 to 5 (5 being very widely used), how widely used do you think operative planning and surgical simulators will be used in the spine in the next 5-10 years?
4. Which spine procedures could benefit most from advances in operative planning and surgical simulators?

## 4.1 Operative Planning and Surgical Simulators

Pre-operative planning will be increasingly used to define the best approach to the anatomy of interest, simulate the results of a surgical intervention, and evaluate the consequences of different approaches. Surgical simulation may be used for training and education, and technical issues include the development of better haptic interfaces.

The major concern here is that the models used in these systems are not as sophisticated as they need to be for realistic results. There are still basic research issues that need to be addressed

in tissue modeling, deformable modeling, biomechanical modeling, and image segmentation. Patient specific models need to be incorporated and available in a timely fashion for operative planning to become clinically useful.

A related concern is that better haptic interfaces for more realistic force and tactile feedback are required. This is partially a function of the model used for force feedback and partially a function of the hardware available. For operative planning, the user interface needs to be intuitive and easy to use so that a physician can operate the system with minimal training.

### 4.2 Intraprocedure Imaging and Endoscopy

This working group includes all the imaging modalities that may be used during procedures including the intraprocedure use of CT, MRI, ultrasound, and fluoroscopy. As intraprocedure imaging becomes more common, the question of which modality is most appropriate for which procedures will continue to arise. The tradeoffs between cost, accuracy, and information provided were discussed. This group also considered the use of endoscopic images in spinal procedures, and the potential for fusing endoscopic images with the 3D imaging capability of CT or MRI.

With respect to technical problems, improvements in hardware developments to reduce size and cost while improving imaging resolution are required. Interventional MRI and the associated instruments are generally seen as too expensive, while other modalities such as CT and fluoroscopy output ionizing radiation. Endoscopy problems include limited visibility, difficulty with knowing where one is in relation to the anatomy, and difficulty in dealing with complications. Two respondents questioned whether endoscopy would play a major role in spine procedures since it may be more applicable to procedures where there are large cavities such as in the abdomen. Finally, registration was also mentioned several times here, and seems to be a pervasive issue.

Most of the respondents felt that intraprocedure imaging and endoscopy would be widely used in the spine in the next 5-10 years. There were 17 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.8. One respondent felt that intraprocedure imaging would be widely used, but endoscopy would not.

### 4.3 Registration and Segmentation

This includes all aspects of registration including 3D/3D registration (such as CT to MRI), 3D/2D registration (CT to fluoroscopy), and registration for instrument tracking. While there has been a great deal of work done in registration and segmentation, the development of easy-to-use, robust, and automatic registration and segmentation algorithms remains an elusive goal.

The major technical problems mentioned with registration include the need for manual intervention, limited robustness, the lack of methods for accurate real-time registration of a non-rigid object, and the limited accuracy of fiducial-free registration methods. For segmentation, most current methods are too slow and too manually intensive. The problem of motion of spine segments between imaging and surgery needs to be addressed. Finally, there is a lack of standards for determining performance requirements, assessing accuracy, and validation of algorithms.

The majority of the respondents felt that registration and segmentation would be widely used in the spine in the next 5-10 years. There were 15 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 4.1. It might have been better to break this question out since most researchers would probably think registration will be widely used, but segmentation may not be widely used.

### 4.4 Anatomic and Physiological Modeling

This includes anatomic and physiological modeling as well as soft tissue modeling such as deformable models. The use of modeling in image-guided procedures is still in its infancy, and fundamental issues remain as to the creation, use, and validation of models. Accurate and reliable models are key to advancing the state-of-the-art in surgical simulation and operative planning, among other areas.

Many respondents felt that current models are not realistic enough, and a fundamental problem in anatomical modeling is soft tissue modeling. In physiological modeling, the complexity of developing an accurate model incorporating phenomena such as hemodynamics was noted. Other issues include the development of patient specific models, computational efficiency, and validation.

There were mixed opinions regarding how much anatomical and physiological modeling would be used in the spine in the next 5-10 years. There were 12 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.1. While some respondents felt it would be very widely used (two scores of 5), others felt it would not be used very much at all (two scores of 1), and others felt it would be used somewhat (three scores of 3).

### 4.5 Surgical Instrumentation, Tooling, and Robotics

Surgical instrumentation includes cages and other devices for fusing the spine. Tooling includes the special purpose devices to access the spine through percutaneous or minimally invasive techniques. In the future, robotic systems may be used to assist in these procedures. These robotic systems may include passive, semi-active, and active systems.

The major technical problems in this area including developing technology that is safe, reliable, and easy to use in the operating room. The equipment should also be compatible with imaging modalities such as MRI and CT. Other problems include accuracy, suitable man-machine interfaces, and real-time navigation. Other factors limiting the use of this technology include cost, liability, and FDA considerations. One respondent noted that it would be better to adapt conventional instruments to this technology rather than attempt to develop new techniques and procedures around this technology. Another respondent noted that economics is a major issue, and there is still a perception that the gain of the technology is minimal compared to the inconvenience and risk.

Most respondents felt that surgical instrumentation, tooling, and robotics would be fairly widely used in the spine in the next 5-10 years. There were 13 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.6. As in previous

questions, it might have been better to break out these technical areas. One respondent gave two scores: a score of 5 to surgical instrumentation and tooling but a score of 2 to robotics.

### 4.6 Systems Architecture, Integration, and User Interfaces

This group defined the architecture for the image-guided spine procedure systems of the future. For example, how should the various technologies such as registration, tracking, and 3D visualization be integrated into a system that the clinician can easily use? What is the appropriate user interface for such a system (3D mouse, heads up display, touch screen, voice operated, eye tracker)? This group also considered various technologies that are not covered by other groups including image-guided surgery systems.

The major technical problem here is creating a system that is powerful yet easy to use. Several respondents commented that current image-guided systems are still too difficult to use in the operating room, and that a technician is required to operate the system in many cases. The user interface is a key issue, and user interface design requires collaboration of experts from different fields. Conveying the information a surgeon needs in a format he/she can use is still a problem.

Other factors limiting the user of these technologies include the lack of complete component technologies, economic justification, and liability issues. The use of different file formats by different medical imaging device manufacturers was also noted as a problem, but this may be resolved by the DICOM medical imaging standard.

Most respondents felt that systems architecture, integration, and user interfaces would be fairly widely used in the spine in the next 5-10 years. There were 10 responses to this question, and on a scale of 1 to 5 (with 5 being very widely used) the average response was 3.8.

## 5.0 Spine Procedures

The responses to question 4 concerning spine procedures are given here across all working groups. The question (for working group 1) was: Which spine procedures could benefit most from advances in operative planning and surgical simulators?

The most frequent responses were percutaneous procedures including screw placement, fusion, biopsies, and bone cement injection. Scoliosis was also frequently listed, as was fusion in general. Other procedures mentioned include cement injection, decompression, deformity surgery, discectomy, disk herniations, endoscopy, free sequesters in the spinal canal, interbody devices, intervertebral disk procedures, multi-segmental procedures, trauma and reconstruction, tumor removal, and wiring.

## 6.0 Acknowledgements

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# Chapter 9

# Investigating 3D Tumor Distribution for Optimized Diagnosis of Prostate Cancer

**Abstract**

Transrectal Ultrasonography (TRUS) based systematic needle biopsy of the prostate has been widely used clinically in the diagnosis of prostate carcinoma. Current protocols for prostate biopsy, such as the Sextant Protocol, however, have been proven to be insufficient in cancer detection since these protocols were built without having accurate information on 3D distribution of prostate cancers. In this research, our goal is to optimize prostate biopsy protocols by statistically investigating spatial distributions of prostate cancers. Based on the low-resolution nature of ultrasound imaging and the current clinical conventions, we propose to divide each individual prostate gland into different zones that are can be recognized and accessed by the urologists with ultrasound images during biopsy. By calculating cancer appearance inside each of these zones using a large number of prostate samples, we get the overall distributions of prostate cancers based on which an optimal biopsy protocol can be developed.

## 1.0 Introduction

Transrectal Ultrasonography (TRUS) guided systematic needle biopsy of the prostate has been widely used clinically for the diagnosis and staging of prostate carcinoma. Due to the low resolution of the ultrasound images, however, a urologist can hardly differentiate abnormal tissues from normal ones during the biopsy. Therefore a number of protocols have been developed to help urologists in doing the prostate needle biopsy, such as the systematic sextant biopsy [7], which designate locations of needles on the prostate as well as number of needles to use. Current screening tests for prostate needle biopsy include prostate specific antigen (PSA) and digital rectal exam (DRE). Age-referenced PSA, PSA
FReportdensity (PSAD) and PSA velocity (PSAV) are also used to determine if a biopsy is necessary. The combination of PSA and DRE tests and a more informed patient and physician population has led to an increased number of prostate needle biopsies.

Recent studies, however, have shown that the accuracy of currently used biopsy techniques needs to be improved [1]. Daneshgari et al. [4] developed a 2-D computer simulation of the prostate based on 159 radical prostatectomy specimens. The computer generated random prostates and tumors. These computer models were used to simulate the sextant biopsy protocol and verify its ability to detect low-volume tumors. Various biases for the angle of biopsy and distribution of cancer foci were incorporated in the model. The simulation showed that only 20.3% of the simulated prostates had a tumor

distribution in which sextant biopsy had a 95% probability of tumor detection. In fact, 26.8% of prostates had a distribution that was completely disjointed from the sextant locations. These prior findings show that a significant number of patients who have prostate cancer are not diagnosed at their initial biopsy. As a result, currently there are a significant number of prostate cancers that are detected on repeat biopsies, which also suggested the need for improvement of current biopsy protocols. Keetch et al. [9] reported a 24% (104/427) positive repeat biopsy rate in men with persistently elevated PSA after initial negative biopsy. Lui et al. [10] reported a higher repeat positive biopsy rate of 38% (72/187). When Ukimura et al. [11] evaluated 226 men that had undergone repeat biopsies for an elevated PSA, 51 men (26%) were found to have prostate cancer on repeat biopsy. Cancers were found in 17% (33/193) of all men on the first repeat biopsy and 26% (14/54) patients who underwent a second repeat biopsy. It is obvious that improving the predictive value of TRUS guided biopsy by optimizing biopsy protocols will significantly improve its value as a diagnostic tool.

Recently, a number of researchers have investigated techniques for improving the accuracy of biopsy protocols. Eskew et al. introduced a 5-region biopsy protocol in which additional lateral and midline biopsies are added systematically to the traditional sextant biopsy [5]. The 5-region biopsy and the traditional sextant biopsy were compared with a total of 119 patients who underwent transrectal ultrasound guided needle biopsy of the prostate. In 48 cancer patients, 17 (35%) were detected only by the additional needles of the 5-region biopsy method within this group. As a result, the new 5-region biopsy method was claimed to improve biopsy results. Our group found that the 5-region protocol showed a statistically significant advantage over the sextant method based on simulation results of 89 patients with cancer [8]. Chang et al. [3] also showed that lateral biopsies increase the sensitivity of prostate cancer detection. Fourteen percent of 118 patients had prostate cancer detected by only the lateral prostate biopsies. Goto et al. suggested that new biopsy strategies could be developed based on probability maps of cancer distribution within the prostate [6]. But issues such as how these maps should be built and how new biopsy protocols could be derived from the maps remain to be investigated.

In this research, our goal is to optimize prostate biopsy protocols based on statistical analysis of a large-scale 3-D biopsy visualization and simulation experiment using 281 3-D prostate surface models that were reconstructed from step-sectioned whole-mounted radical prostatectomy specimens with localized cancers. In combination, spatial distribution of the prostate tumors will also be initially investigated with the 281 3-D models in such as a way that will help directly determine an optimized protocol for improved cancer detection. Based on the low-resolution nature of ultrasound imaging and the current clinical conventions for TRUS guided prostate biopsy, we propose to divide a prostate gland into different zones (instead of individual points) that are accessible by the urologists under the guidance of ultrasound images. By calculating cancer appearance inside these zones, we will have overall spatial distribution of prostate cancers based on which an optimal biopsy protocol might be developed.

## 2. 0 Approaches and Results

We have developed a deformable modeling technique for the reconstruction of 3D prostate surface models based on whole-mount step-sectioned radical prostatectomy specimens, and used it in a prostate biopsy simulation system [12, 13, 2]. In total, two hundred and eighty one 3D prostate models have been reconstructed until now. We have also developed a new algorithm that can divide each individual prostate model into a specific number of zones, such as posterior and anterior zones, base, mid and apex zones. We have calculated cancer distributions for all the 280 prostate models with a detailed 48-zone division. Looking at a prostate in axial view, this algorithm divides a prostate gland into 4 symmetric compartments sideways, 4 symmetric compartments vertically, and 3 compartments in depth. An example of a prostate model with 48-zone division is shown in Figure 1. The size of the zones will vary with the size of a prostate model. A larger prostate ends up with having a larger size for each of its 48 zones. This variation of zone sizes is the natural reflection of the original prostate, and it does not affect the accuracy of tumor distributions.

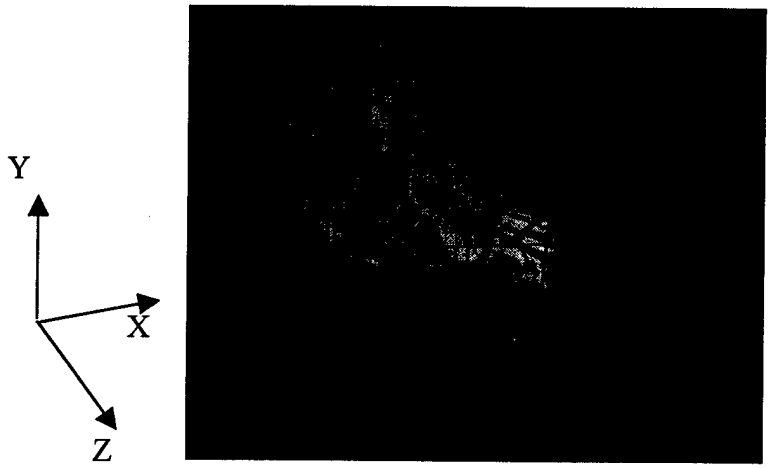
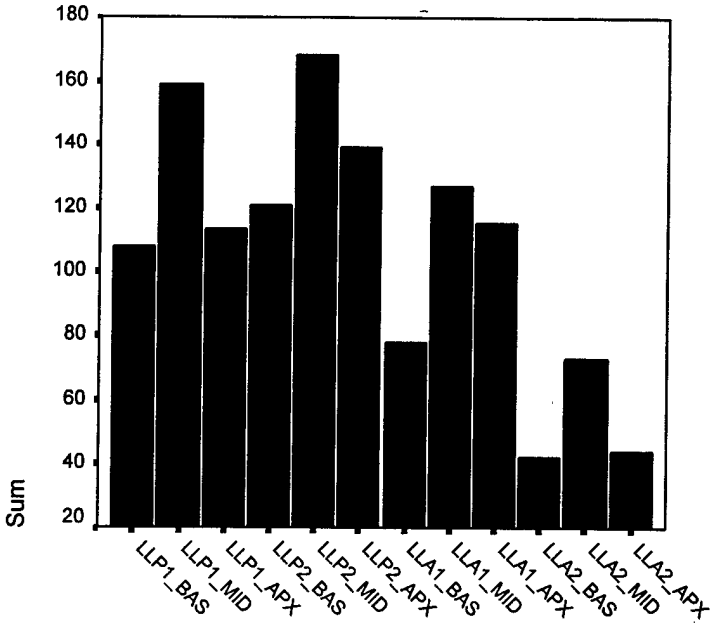


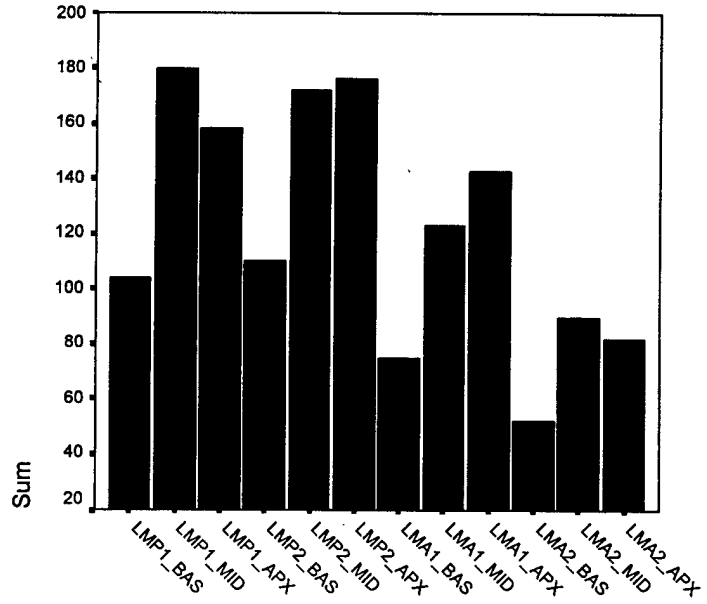

Figure 1 A prostate model with 48-zone division

The labeling of each zone follows the current clinical conventions. The four layers of zones parallel to the YZ plane (sagittal) are labeled along the positive X direction as: left lateral (ll), left mid (lm), right mid (rm) and right lateral (rl), respectively. The three layers of zones parallel to XY plane (axial) are labeled along the positive Z direction as: base, mid and apex, respectively. Similarly, the four layers parallel to the XZ plane (coronal) are labeled along the positive Y direction as: posterior 1 (p1), posterior 2 (p2), anterior 1 (a1) and anterior 2 (a2), respectively. When a specific zone is labeled, the labels of the corresponding three layers are combined in the X-Y-Z order. For example, the zone 'A' in Figure 1 is labeled as llp1-apex.

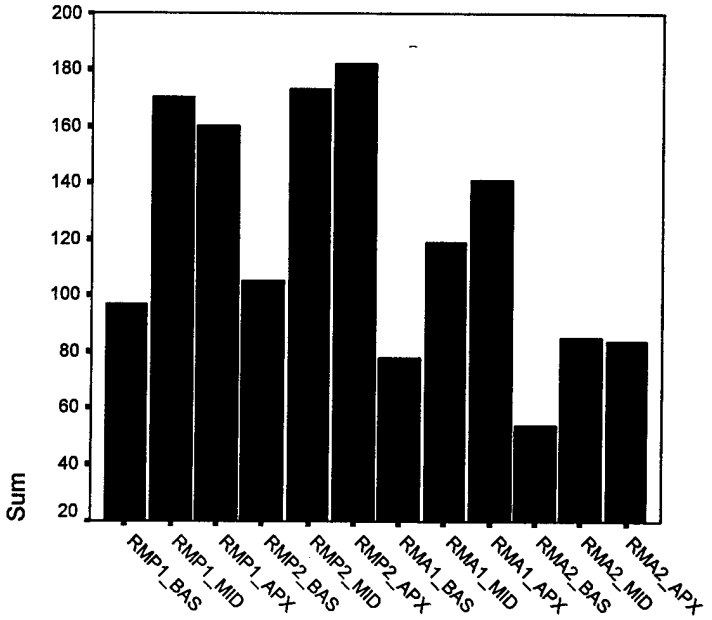
In order to investigate the tumor distribution inside the prostate gland, we have calculated the appearance of tumors in each zone of each of the 281 individual prostate models. The results are presented in sagittal layers (Figure 2) and coronal layers (Figure 3).



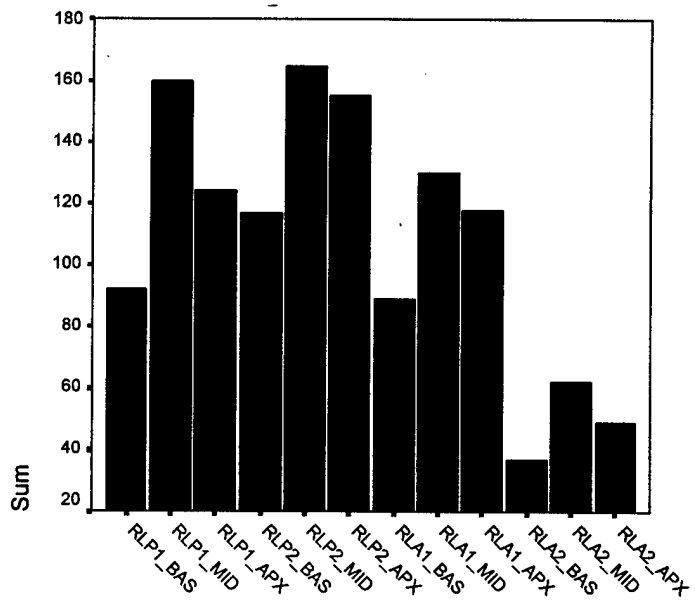

(a) Tumor distribution at left lateral layer




(b) Tumor distribution at left mid layer




(c) Tumor distribution at right mid layer




(d) Tumor distribution at right lateral layer

Figure 2 Tumor distribution presented in sagittal layers

| | | |
|---|---|---|
| rl-base 32.74% | rl-mid 56.94% | rl-apex 44.13% |
| rm-base 34.52% | rm-mid 60.50% | rm-apex 56.94% |
| lm-base 37.01% | lm-mid 64.06% | lm-apex 56.23% |
| ll-base 38.43% | ll-mid 56.58% | ll-apex 40.21% |

(a) Distribution at posterior 1

| | | |
|---|---|---|
| rl-base 41.64% | rl-mid 58.72% | rl-apex 55.16% |
| rm-base 37.37% | rm-mid 61.57% | rm-apex 64.77% |
| lm-base 39.15% | lm-mid 61.21% | lm-apex 62.63% |
| ll-base 43.06% | ll-mid 59.79% | ll-apex 49.47% |

(b) Distribution at posterior 2

| | | |
|---|---|---|
| rl-base 31.67% | rl-mid 46.26% | rl-apex 41.99% |
| rm-base 27.76% | rm-mid 42.35% | rm-apex 50.18% |
| lm-base 26.69% | lm-mid 43.77% | lm-apex 50.89% |
| ll-base 27.76% | ll-mid 45.20% | ll-apex 40.93% |

(c) Distribution at anterior 1

| | | |
|---|---|---|
| rl-base 13.17% | rl-mid 22.06% | rl-apex 17.44% |
| rm-base 19.22% | rm-mid 30.25% | rm-apex 29.89% |
| lm-base 18.51% | lm-mid 32.03% | lm-apex 29.18% |
| ll-base 14.95% | ll-mid 25.98% | ll-apex 15.66% |

(d) Distribution at anterior 2

Figure 3 Tumor distribution presented in coronal layers

From Figures 2 and 3, the following results can be easily drawn. (1) It is obvious that the base zones have significantly less tumor distribution than the other corresponding zones. (2) Similarly, the anterior zones have much fewer tumors than their counterparts in the posterior zones. (3) In general, the mid and apex zones have comparable amount of tumor distribution. Note that in Figures 2(a) and 2(d), although the apex zones show less tumor distribution than the corresponding mid zones, this is mainly due to the difference in physical space of the prostate gland.

More analysis is being conducted using these data. In addition, racial difference in tumor distribution is also being analyzed. Based on this research, some optimized needle biopsy protocols will be developed, and then compared and evaluated against those that are currently widely used clinically. Furthermore, staging using biopsy results is also under research, such as estimation of prostate tumor size *in vivo* using needle tumor core volumes and other factors. We are exploring both statistical methods and GA (genetic algorithms) based neural networks methods for this purpose. In the near future, we will

also investigate image guided prostate needle biopsy and other procedures using the 3D prostate models and tumor distribution information we have developed.

## 3.0 Conclusions

Tumor distribution of the prostate provides the urologists with significant useful information for performing needle biopsy. Compared to traditional biopsy protocols, the new protocols to be developed based on tumor distribution information will be substantially accurate in terms of tumor detection. The clinical impact is expected to be significant as this research continues to develop and improve these new biopsy protocols.


## Acknowledgements

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# Chapter 10

# IN 3-D COMPUTER SIMULATED PROSTATE MODELS LATERAL PROSTATE BIOPSYS INCREASE THE DETECTION RATE OF PROSTATE CANCER

**Keywords**: 3-D simulation, cancer distribution, computer visualization and simulation, interactive prostate needle biopsy

**ABSTRACT**

**Objectives.** Urologists routinely use the systematic sextant needle biopsy technique to detect prostate cancer. However, recent evidence suggests that this technique has a significant sampling error. We developed a novel 3-D computer assisted prostate biopsy simulator based upon whole-mounted step-sectioned radical prostatectomy specimens to compare the diagnostic accuracy of various prostate needle biopsy protocols.

**Methods.** We obtained digital images of 201 step-sectioned whole-mounted radical prostatectomy specimens. 3-D computer simulation software was developed to accurately depict the anatomy of the prostate and all individual tumor foci. Additional peripheral devices were incorporated in the system to perform interactive prostate biopsies. We obtained 18- biopsies of each prostate model to determine the detection rates of various biopsy protocols.

**Results.** The 10- and 12- pattern biopsy protocols had a 99.0% detection rate, whereas, the traditional sextant biopsy protocol rate was only 72.6%. The 5-region biopsy protocol had a 90.5% detection rate and the 14- pattern, which includes all the biopsies used in the patterns above only added one additional positive case (99.5%). Transitional zone and seminal vesicle biopsies did not result in a significantly increased detection rate when added to the patterns above. Only one The lateral sextant pattern revealed a detection rate of 95.5%, whereas, the 4-pattern lateral biopsy protocol had a 93.5% detection rate.

**Conclusions.** Our results suggest that all the biopsy protocols that use laterally placed biopsies based upon the five region anatomical model are superior to the routinely used sextant prostate biopsy pattern. Lateral biopsies in the mid and apical zones of the gland are the most important.positive model was obtained when the transitional biopsies were added.

## 1.0 Introduction

Transrectal ultrasound (TRUS) guided biopsy is routinely used for diagnosis of prostate cancer. The current biopsy protocol routinely used by urologists is the systematic sextant biopsy (1). However, studies have shown that this protocol results in a positive detection rate of only 20-30% (2, 3). Furthermore, a significant number of patients (20-40%) with elevated PSA have a positive repeat biopsy, suggesting that many patients with prostate cancer are not being diagnosed initially using the sextant protocol (4-7). Recent clinical studies have suggested that the sextant technique may not be optimal and have investigated new biopsy protocols that may yield significantly better results (8-10).

Recently, studies using computer simulation of prostate biopsies have been published suggesting that additional biopsies can increase the sensitivity of the procedure. Both two-dimensional (2-D) and three- dimensional (3-D) computer-based simulation of prostate cancer have been shown to be useful in evaluating existing biopsy protocols (11-14). The objective of our study was to use a large number of 3-D reconstructed radical prostatectomy specimens to determine the detection rate of previously investigated biopsy protocols and, additionally, to

determine the frequency of positive biopsies in various regions of the prostate in order to develop an optimized biopsy protocol. Since the new biopsy protocol will be based on statistical analysis of a quantitative database of digitized radical prostatectomy prostate specimens, it may significantly improve the accuracy of prostate cancer detection.

## 2.0 Methods

### 2.1 Construction of individual 3-D computerized prostate models

Individual 3-D prostate models are constructed from radical prostatectomy specimens. The prostates are step-sectioned using a deli slicer at 2.25mm intervals and then digitized with a scanning resolution of 1,500 dots per inch. Each digitized image is segmented by a single pathologist (IAS) to identify the key pathological structures including surgical margins, capsule, urethra, seminal vesicles and tumor. The contours of each structure are identified on each slice then stacked to develop the 3-D prostate model. Interpolation between the contours is carried out using a 3-D elastic model-based technique. Two hundred and one 3-D individual prostate models have been constructed using an SGI Onyx 2 Infinite Reality 10000 Workstation (figure 1). An interactive biopsy interface was developed to allow real-time rotation and insertion of the ultrasound probe, and depth of needle placement before the biopsy device was fired (figure 2).

### 2.2 Biopsy needle placement

A single urologist (JJB) completed a total of 18 biopsies on each of the 201 prostate models. The various regions of the prostate were sampled a similar manner. Biopsies were performed in the right and left apex, mid and base regions of the prostate models (sextant protocol) half way between the midline and the lateral edge of the prostate. Additional biopsies in the lateral aspect of the right and left apex, mid and base regions were obtained midway between the sextant biopsy locations and the lateral border of the prostate (lateral biopsies). To incorporate a 5-region biopsy pattern similar to Eskew et al (9) biopsies in the midline apex and base were obtained. Both the right and left transition zone and seminal vesicles were also sampled. The tip of the needle was brought up to the capsule of the prostate at a 30-degree angle and then discharged in the interactive mode (Figure 3). The computer then automatically determined if the biopsy was positive for tumor. Several patterns were analyzed as defined in table 1.

### 2.3 Data analysis

Frequencies of positive biopsies in the various prostate regions were determined. The mean positive biopsy hits were calculated for each biopsy protocol. The needle core biopsy data for each biopsy protocol was analyzed for variance using the McNemar's test.

## 3.0 Results

Table 2 is a summary of the individual positive biopsy frequencies for each region of the prostate. Of the 201 prostate models, both the 10- and 12- pattern biopsy protocols detected cancer in 199 models for a detection rate of 99.0%. In comparison, the sextant (6-pattern) biopsy protocol only detected 146 models with cancer (72.6%). As noted in table 1, with the addition of the laterally placed biopsies, the 10-, 12-, 14-, 16- pattern and 5-region biopsy protocols have a higher detection rate. The extra biopsies used in the 14- pattern biopsy protocol only added one additional positive model where cancer was detected (99.5%). The 5-region biopsy protocol had a positive detection rate of 90.5% (182/201). The transitional zone and seminal vesicle biopsies added little to the detection rate. One model was detected with cancer solely by the transitional zone biopsy (0.5%, 1/201). The seminal vesicle biopsies where never positive when all other biopsies were negative. The overall positive frequencies for the transitional zone biopsies were 26/201(12.9%) models on the left, 23/201(11.4%) models on the right and for the seminal vesicle biopsies were 2/201(1.0%) models on the left and 3/201(1.5%) models on the right. Interestingly, the lateral sextant 6-pattern and the 4-pattern had a significantly higher detection rate that the traditional sextant pattern (93.5%, 95.5%, 72.6%, respectively).

We analyzed for variance using the McNemar's test. A 2 x 2 table of two different biopsy patterns was constructed and then compared. For example, comparison of the sextant to lateral sextant biopsy is shown in table 3. In constructing this table, the question of interest is whether the detection rate for sextant pattern (146/201 = 72.6%) and the lateral sextant pattern (192/201 = 95.5%) are the same. The McNemar's test only analyzes the discordant elements of the 2 x 2 table, these are the data points that are important in determining whether there is a significant difference. In our example, the test statistic is $(53\text{-}7)^2/(53+7) = 46^2/60 = 3.267$, which is the approximate Chi-square with 1 df (degree of freedom). For Chi-squared (35.3), the p-value is equal to 0.001, so we reject the null hypothesis of equal detection rates. The lateral sextant biopsy patterns detection rate was significantly better than the traditional sextant biopsy. We then compared the 4- pattern biopsy (R/L lateral apex and lateral mid) to the lateral sextant pattern and found the lateral sextant to be marginally better with a p=0.046. Subsequent comparisons were as follows: lateral sextant vs. 10-pattern (p=0.008, in favor of the 10-pattern), 10 vs. 12-pattern (no difference, in favor of 10- since lower number of biopsies), 10 vs. 14-pattern (p=0.317, no significant difference, in favor of the 10-pattern with lower number of biopsies) and 10-pattern vs. 5-region pattern (p=0.001, in favor of the 10- pattern). These results suggest that the 10-pattern biopsy protocol is the optimum pattern for the detection of prostate cancer.

## 4.0 Comment

Our study supports the routine use of laterally placed biopsies and suggests the transition zone and seminal vesicle biopsies are rarely required to detect prostate cancer if lateral biopsies are used. The transition zone biopsies were positive in only one model when all other biopsies were negative. There were no models that were positive in only the seminal vesicles. Considering the significant amount of pain that may be associated with transitional zone biopsies, biopsy protocols that include lateral biopsies should decrease the overall patient discomfort of prostate biopsy. When comparing the various patterns, the traditional sextant biopsy pattern revealed a cancer detection rate of 72.6 % in 201 prostate models. By merely shifting these six biopsies laterally one obtains a significantly higher cancer detection rate (95.5% vs 72.6%). In fact, the 4- pattern, a subset of the lateral biopsies which includes the right and left lateral apex and lateral mid region biopsies approximate the detection rates of the biopsy protocols that use 10, 12, 14, or 16 biopsies (93.5% vs 99.0%, 99.0%, 99.5%, %, 100%, respectively). However, our statistical analysis of the various biopsy patterns suggests that the 10-pattern biopsy protocol is the most optimum systematic biopsy protocol. It is also very important that the biopsies are obtained along the posterior and lateral surface of the prostate. The majority of tumors in our radical prostatectomy specimens were near the posterior and lateral capsule. If one merely seats the needle into the prostate before biopsy, a significant number of the needle cores would have been negative.

Current screening tests for prostate cancer include prostate specific antigen (PSA) and digital rectal exam (DRE). The combination of these two tests and a more informed patient and physician population has led to an increased number of prostate needle biopsies. However, with a 20-30% detection rate the accuracy of currently used biopsy techniques needs to be improved. There are also a significant number of prostate cancers that are detected on repeat biopsies. Keetch et al. (5), reported a 24% (104/427) positive repeat biopsy rate in men with persistently elevated PSA after initial negative biopsy. Lui and associates (15), reported a higher repeat positive biopsy rate of 38% (72/187). Lui's study additionally identified that 28% (53/187) of the repeat biopsies had cancers detected in the peripheral zone and 10% (19/187) in the transitional zone. When Ukimura and associates (16) evaluated 226 men that had undergone repeat biopsies for an elevated PSA, 51 men (26%) were found to have prostate cancer on repeat biopsy. Cancer was found in 17% (33/193) of all men on the first repeat biopsy and 26% (14/54) patients who underwent a second repeat biopsy. Repeat biopsy has potential morbidity and contributes significantly to the costs of detecting prostate cancers. With such a high incidence of positive repeat biopsies many other techniques have been evaluated to determine the patient that would have a higher probability of a repeat positive biopsy. The majority of these indices were used to distinguish between benign prostatic hypertrophy and prostate cancer. Age-referenced PSA, PSA density (PSAD) and PSA velocity (PSAV) are still used to determine if a biopsy is necessary. Currently, the ratio of free-to-total PSA for patients with a PSA value between 4-10 ng/ml is increasingly being used to determine the risk of prostate cancer after an initial negative biopsy (4,17). Morgan et al. showed that a low ratio, despite multiple negative biopsies, demonstrated significant predictive power. A 10% cutoff provided 91% specificity and 86% specificity.

Daneshgari et al (11), developed a 2-D computer simulation of the prostate based on 159 radical prostatectomy specimens. The computer then generated random prostates and tumors. This computer model was used to simulate the sextant biopsy protocol and verify its ability to detect low-volume tumors. Various biases for the angle of biopsy and distribution of cancer foci were incorporated in the model. The simulation showed that only 20.3% of the simulated prostates had a tumor distribution in which sextant biopsy had a 95% probability of tumor detection. In fact, 26.8% of prostates had a distribution that was completely disjointed from the sextant locations. These prior findings show that a significant number of patients who have prostate cancer are not diagnosed at their initial biopsy. Accordingly, improving the predictive value of TRUS guided biopsy by optimizing biopsy protocols will improve its value as a screening and diagnostic tool.

A number of researchers have investigated techniques for improving the accuracy of biopsy protocols; however, several issues remain to be resolved. Eskew et al. introduced a new protocol called the 5-region biopsy in which additional lateral and midline biopsies are added systematically to the traditional sextant biopsy (9). The 5-region biopsy and the traditional sextant biopsy were compared with a total of 119 patients who underwent transrectal ultrasound guided needle biopsy of the prostate. In 48 cancer patients, 17 (35%) were detected only by the additional needles of the 5-region biopsy method within this group. As a result, the new 5-region biopsy method was claimed to improve biopsy results. Eskew's results are promising, but his study group of 48 patients is small. Therefore, this protocol needs to be validated, and the underlying rationale for using 12 needles instead of some other number should be examined.
Our group found that the 5-region protocol showed a statistically significant advantage over the sextant method based on 89 patients with cancer (13). Chang et al. (10), also showed that lateral biopsies increase the sensitivity of prostate cancer detection. Fourteen percent of 118 patients had prostate cancer detected by only the lateral prostate biopsies. Dietrick et al. conducted a clinical study of 110 men who underwent radical prostatectomy and compared the core cancer length with the volumes of clinically significant and incidental carcinoma (18). For sextant biopsies, Dietrick determined that an optimal biopsy core length of 3 mm or more could reliably detect cancer of clinically significant volume. Vashi et al. developed a statistical model that determined the optimal number of biopsies to achieve a 90 % certainty of detecting various volumes of life threatening cancer (19). This model incorporated the variables of tumor doubling time, age, and prostate volume. Patients with prostate volumes greater than 20 grams and aged 50-69 years required an increased number of biopsies (7-23 biopsies) to detect life threatening prostate cancers. Goto et al. suggested that new biopsy strategies could be developed based on probability maps of cancer distribution within the prostate (9). But issues such as how these maps should be built and how new biopsy protocols could be derived from the maps remain to be investigated.

Recently, the use of 3-D computer simulation has supported the use of lateral biopsies as an essential component in any protocol to increase the detection rate of prostate cancer. Karakiewicz et al, using a 3-D computer assisted analysis of sector biopsies, showed that as they increased the number of biopsies from 4 to 12 and incorporated lateral zone biopsies the detection rates increased (11). This was especially true for the larger volume prostates. Chen et al. and Kaplan et al. both used 3-D computer simulations of prostate biopsy based upon

reconstructed radical prostatectomy specimens (12, 13). Both studies showed that the sextant protocol was less sensitive (~ 20%) than biopsy patterns that used an increased number of cores and laterally placed biopsies.

## 5.0 Conclusion

The accurate 3-D reconstruction of the radical prostatectomy specimens with spatial anatomy that includes the urethra, ejaculatory ducts, seminal vesicles, capsule, surgical margins and the tumors allows for evaluation of various prostate biopsy protocols. In general it was noted that the majority of the tumors were near the posterior-lateral surface of the prostate. The laterally placed biopsies in the posterior-mid and posterior-apex regions of the gland resulted in the highest positive biopsy frequencies, all near 50%. It is important to note that actually placing the tip of the needle into the prostate before the biopsy is performed results in a higher negative biopsy rate since the tumors are so close to the posterior and lateral capsule.

When we compared the various biopsy patterns our results suggest that the 10-pattern biopsy protocol provides the highest relative detection rate for the number of biopsies performed during a single procedure. When compared to the 10-pattern protocol, the additional biopsies of the 12-, 14-, 16- and 5-region biopsy protocols do not add significantly to the detection rate. The lateral 6-pattern and the 4-pattern biopsies approximate the detection rates of the patterns with higher numbers of biopsies. If clinicians are reluctant to adopt the 10-pattern biopsy protocol because of the extra biopsies, then merely using a sextant pattern with laterally placed locations will approximate the detection rate. Prospective clinical trials that compare these biopsy protocols must be completed to validate these results before any definitive recommendations can be made to replace the currently used traditional sextant biopsy protocol.

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# Table 1.

**Biopsy Pattern Definitions and Detection Rates**

| | | tection te (%) | # of Biopsies |
|---|---|---|---|
| **4-pattern:** | R/L lateral Apex and lateral Mid | 93.5 | 4 |
| **6-Pattern:** | Sextant = R/L Base + R/L Mid + R/L Apex | 72.6 | 6 |
| **6L-Pattern:** | Lateral Sextant = R/L lateral apex, mid, base | 95.5 | 6 |
| **10-Pattern:** | 6-Pattern + R/L lateral Mid + R/L lateral Apex | 99.0 | 10 |
| **12-Pattern:** | 10-Pattern + R/L lateral Base | 99.0 | 12 |
| **14-Pattern:** | 12-Pattern + Middle Base + Middle Apex | 99.0 | 14 |
| **5-Region:** | 6-Pattern + Middle Base + Middle Apex + R/L lateral Base + R/L lateral Apex | 90.5 | 12 |
| **TZ:** | R/L transitional zone | - | 2 |
| **16-Pattern:** | 14-Pattern + TZ zone biopsies | 100.0 | 16 |
| **SV:** | R/L seminal vesicle | - | 2 |

# Table 2:

**Needle Biopsy Frequencies by Prostate Regions**

| Prostate Region | Negative | Positive | % Positive |
|---|---|---|---|
| | | | |
| ****LEFT**** | | | |
| **Base** | 152 | 49 | 24.4 |
| **Mid** | 111 | 90 | 44.8 |
| **Apex** | 133 | 68 | 33.8 |
| | | | |
| **Lateral Base** | 126 | 75 | 37.7 |
| **Lateral Mid** | 83 | 118 | 58.7 |
| **Lateral Apex** | 99 | 102 | 50.7 |
| | | | |
| ****RIGHT**** | | | |
| **Base** | 160 | 41 | 20.4 |
| **Mid** | 130 | 71 | 35.3 |
| **Apex** | 140 | 61 | 30.9 |
| | | | |
| **Lateral Base** | 139 | 62 | 30.8 |
| **Lateral Mid** | 106 | 95 | 47.8 |
| **Lateral Apex** | 105 | 96 | 47.8 |

| | | | |
|---|---|---|---|
| ***MIDDLE*** | | | |
| **Base** | 164 | 37 | 18.4 |
| **Apex** | 155 | 46 | 22.9 |
| | | | |
| **Transition Zone** | | | |
| **Right** | 178 | 23 | 11.4 |
| **Left** | 175 | 26 | 12.9 |
| | | | |
| **Seminal Vesicle** | | | |
| **Right** | 198 | 3 | 1.5 |
| **Left** | 199 | 2 | 1.0 |
| | | | |

# Table 3:

**McNemar's Test: Comparison of Sextant vs. Lateral Sextant Biopsy Protocols**

| | | Lateral Sextant | |
|---|---|---|---|
| **Sextant Biopsy** | **NO** | **YES** | **TOTAL** |
| **NO** | **2** | **53** | **55** |
| **YES** | **7** | **139** | **146** |
| **TOTAL** | **9** | **192** | **201** |

**NO= negative biopsy, YES= positive biopsy,**
**McNemar's test compares the two biopsy patterns ability to detect cancer in a single model, these individual values are then evaluated as part of the entire cohort. Possible combinations are: NO, NO; NO, YES; YES, YES; and YES, NO, where the two discordant pairs are when the two biopsy patterns differed in their ability to detect cancer in a single model. The discordant pairs are the terms used to figure if the two patterns are different.**

# FIGURES:

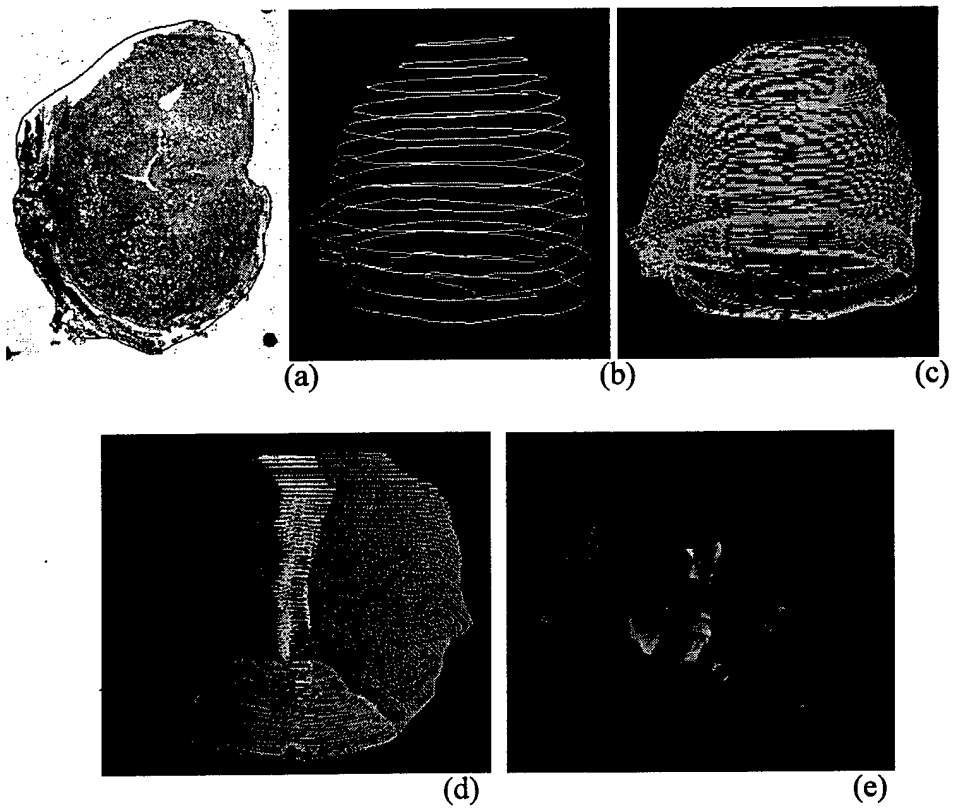



Figure 1: 3-D Reconstruction of Prostate Models (a) Digitized image of a single slice of a step-sectioned radical prostatectomy specimen (b) Stacked surgical margin contour controls of original slices (c) Surgical margin contour interpolation (d) Complete interpolated model with internal structures (e) Final 3-D reconstructed prostate model.

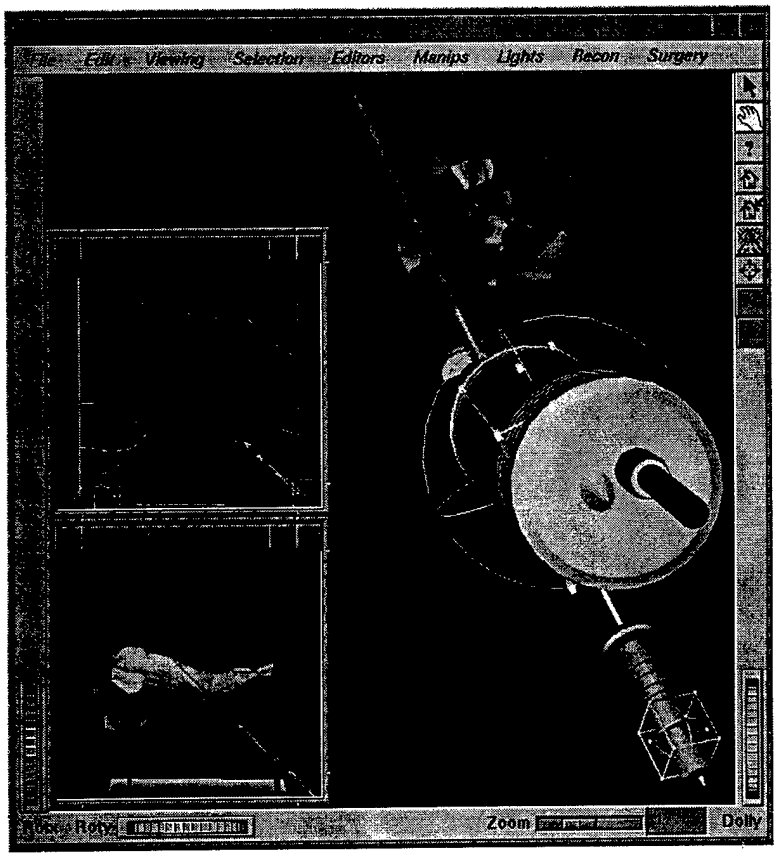
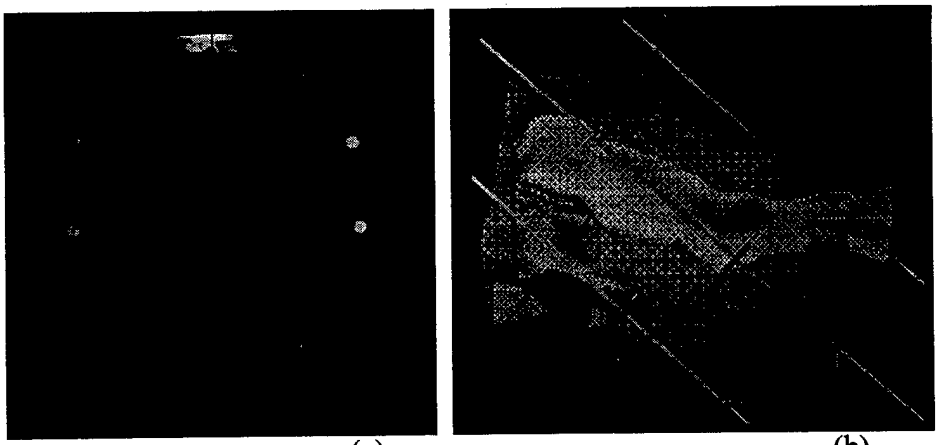



Figure 2: Virtual Interactive Biopsy Graphical User Interface



(a) (b)

Figure 3: Biopsy Locations (a) Colored dots represent the areas of the prostate biopsied, the pink dots correspond to the traditional sextant locations, transition zone and seminal vesicle biopsies not shown (b) Transparent final prostate model with the angle of biopsy path and position of the needle core when the needle is brought up to the capsule, but not seated in the glad. Mid gland biopsies are positioned at a point where half the volume of prostate is above and below the angle

of biopsy path. Apex and Base biopsies are half way between the Mid biopsy and the base and apex of the gland.

# Chapter 11

# Tactile Mapping of Breast Palpation for Diagnosis, Documentation and Training


**ABSTRACT**

Breast palpation by clinicians is an effective examination frequently performed for cancer detection and treatment monitoring. The utilization of physical breast examination however has been hampered by its inherent subjective nature leading to (1) the difficulty in interpreting the examiner's impressions of the perceived lump in the breast and (2) the difficulty in documenting tactile characteristics of the tumor for subsequent examinations or monitoring. The primary objective of the project is to advance an effective *tactile mapping device* (TMD) for a quantitative and objective characterization of breast cancer through breast palpation, showing that the TMD will improve physical breast examination in the ability to characterize tumor's biomechanics and increase the efficacy of early detection and treatment monitoring, thus leading to an improved diagnosis and a reduction in breast cancer mortality. In particular, we are developing (1) a TMD with various resolutions and sizes to quantitatively document the locations and extract the tactile features of the detected breast lumps; (2) a neural network based intelligent system to estimate and track the changes (sizes and depths) of the tumors across time in diagnosis and treatment; and (3) an interactive training program to improve examiner's skill in performing effective breast palpation in how best to search with optimal applied forces.



**Key words**: Breast examination, cancer detection, treatment monitoring, tactile imaging, neural networks, telemedicine.


## 1.0 Significance

Palpation is the most effective and inexpensive method for the detection of breast cancer and assessment of the treatment outcome [1,2,3,5]. Since the most common symptom of breast cancer is a lump, previous studies have shown that the majority of breast cancers are found by palpation [20]. Clinical Breast Examination (CBE) is an important tool for physicians in the diagnosis of breast cancer and assessment of a particular treatment plan, and women are advised to perform breast self-examination (BSE) monthly [1,2,3,21,23]. Recent studies have found that as many as 16% of cancers that were detected by physical examination were not apparent on mammograms [19,20]. Thus, one of the nation's major cancer control objectives for the year 2000 is to increase the frequency and efficacy of physical breast examinations for breast cancer screening and early detection [1].

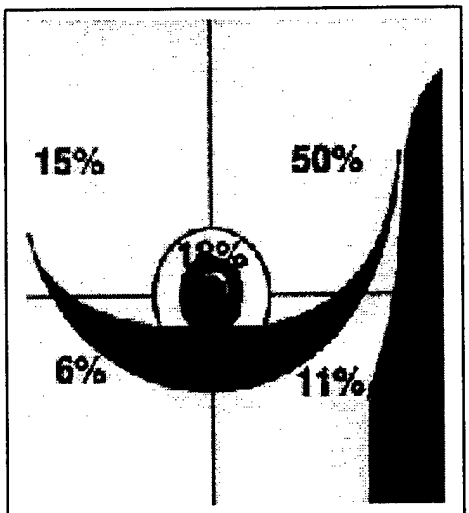


Figure 1. Probability map of breast cancer spatial distributions.

Recent literature strongly supports the complementary role of breast palpation to mammography [3]. For example, given the ability of mammography (including newly developed digital mammography) in detecting small breast cancers, breast palpation can evaluate breast tissue near the chest wall and axilla that is not accessible to mammography (see Figure 1) and can detect cancers in the intervals between screening mammography. Based on one of the largest prospective trials of screening mammography by Swedish Two-County Study [3], Tabar's group has reported that, between ages 40-49, 149 cancer cases were detected by screening mammography; 14 of these patients died in the subsequent 10 years. In the 11 months following this screening mammogram, 32 women presented with interval cancers based on BSE and/or symptoms assessed by CBE. There were 10 deaths in this group. For ages 50-59, 258 cases were detected by mammography screening and in the next 10 years there were 25 deaths. In the first 11month interval, 19 cases of cancer presented with 3

deaths during 10 years of follow-up. This indicates that breast palpation can find small cancers compatible with long survival, and there are cancer cases that are missed on mammography screening that will be detected in the interval between screening mammograms by breast palpation. Furthermore, other data has suggested that there are cases of breast cancer that grow rapidly enough so that the annual mammography is not sufficient and that interval screening by breast palpation is required. It has also been indicated that breast palpation is especially useful in younger women in whom mammography is known to have a lower detection rate based on increased breast density. For example, in Tabar's study, the sensitivity for cancer detection in women under age 50 was 68% [3]. Feig's group has reviewed multiple screening trials and reported that 10% of cancer cases were found by CBE alone, rather than mammography. Rimer's group at Duck thus summarized the results of multiple screening studies which estimates that the added benefit of CBE in mammography screening programs is 5 to 20% of the total cancers detected and that CBE alone provides 50-67% of the value of studies that have combined CBE and mammography. In addition, without a quantitative tactile characterization capability, documentation of detected breast lumps is a difficult task in current physical breast examination. For example, a physician may determine that a palpable abnormality is unlikely to be cancerous but that continued monitoring is indicated. This requires maintaining a record of the examination results, which at present is limited to verbal notes about parameters such as the position, size, and hardness of the lump. Because it is difficult to verbalize tactile sensations, the subjective and arbitrary nature of these notes makes effective follow-up exams problematic. The 1997 Society of Surgical Oncology Practice Guidelines [4] support our clinical experience drawn from those patients referred to use that once a breast lump is found, it should be biopsied or followed. For solid masses in women less than 35 years of age: "If true dominant mass (discrete, different from other nodularity), refer to surgeon. If vague nodularity, thickening or asymmetry, repeat examination in one to two menstrual cysts approximately 1-2 weeks after menstrual period." Similar recommendations are given for women over age 35, but with the added recommendation for a mammogram. In the same Guidelines, it recommends that the surgeon "Distinguish between dominant breast masses requiring biopsy and prominent glandular nodularity that can be safely observed." Thus, a quantitative tactile measurement should be an important feature of this observation. Another problem is that palpation techniques are of variable and largely unknown quality. Training is primarily performed using rubber breast models, and no quantitative feedback is provided to the trainee [16]. This makes it difficult to teach the appropriate forces and search strategies essential for an effective palpation [19,23]. Improving training in BSE is particularly important because patients often cite a lack of confidence in their ability to detect tumors as a reason for not adhering to a regular BSE regime [25,26,27].

We propose to advance tactile characterization of breast palpation and solve the associated clinical problems through the development and application of new tactile mapping technology. The proposed TMD will measure three key variables during palpation: the detected lesion's location, the small-scale pressure variations at the skin due to lumps, and the applied forces. By focusing three clinical applications: diagnosis (for cancer detection), documentation (for subsequent examination and treatment monitoring with high specificity), and training (for improving sensitivity), this research addresses an important but neglected issue. The proposed project promises to improve the effectiveness of breast palpation, and thus increase early detection and reduce mortality. This work will result in: (1) a better understanding of breast palpation techniques from quantitative measurements; (2) a means to document palpation findings for subsequent examinations and treatment monitoring, and (3) improved skill in breast exams through interactive training. We anticipate that improving the skill of patients in BSE will also facilitate more frequent and effective examinations. Health care costs will be reduced because tactile documentation will permit meaningful comparative examinations, so that breast masses which are unlikely to be cancerous can be monitored across extended periods of time without unnecessary and expensive evaluation procedures. Finally, because the systems are based on inexpensive technologies, they will be readily adaptable for use in a large number of clinics and outreach programs.

## 2. 0 Summary of the Specific Aims

The **primary objective** of the project was to adapt new tactile sensing technologies to the needs of improving physical breast examination and gather preliminary data regarding potential clinical applications. A novel and effective *tactile mapping device* (TMD) has been developed to quantitatively characterize breast cancer through breast palpation so as to demonstrate the feasibility and effectiveness of the TMD to the three specific applications: diagnosis, documentation, and training. Limited laboratory experimental evaluation and pre-clinical trial have been conducted to collect preliminary data that will permit formation of a full-scale research plan. Our considerable **effort** in the research is twofold:

A. To fully and progressively meet the objectives and demonstrate the feasibility with convincing evidence.

A.1 *Prototype System Development*: We have developed, calibrated, and pilot tested a novel TMD by integrating state-of-the-art tactile pressure sensor, force/torque sensor, and 3D visual tracking technologies, and conducted laboratory experiments and limited pre-clinical trial to evaluate TMD's performance in terms of reliability, validity, and safety.

A.2 *Application in Documentation*: We have applied the TMD to generate the tactile images of the detected breast lumps for a quantitative and objective characterization of breast cancers in subsequent examinations, and evaluated TMD's performance in improving diagnosis in terms of reproducibility, sensitivity, and specificity for different cases/users/exams.

A.3 *Application in Training*: We have studied the feasibility of TMD for training of examiners in performing physical breast examination, through the use of a computerized interactive training system, with the purpose of improving the trainees' ability in how best to search palpable abnormalities with optimal forces in detecting smaller tumors.

B. To actively enhance the scientific merit of the phased research.

B.1 *System Development*: We discussed the spatial resolution and sensitivity of tactile sensor array, where both small but higher resolution and more coverage but lower resolution tactile sensor arrays are considered, and multiple finger palpation is used. We have also addressed the advantages and limitations of the sensors and the associated algorithms with respect to the detection capability and accuracy for deeper or smaller lesions.

B.2 *System Evaluation*: We addressed the correlation of size estimates (TMD and CNN) with pathological findings (MRI

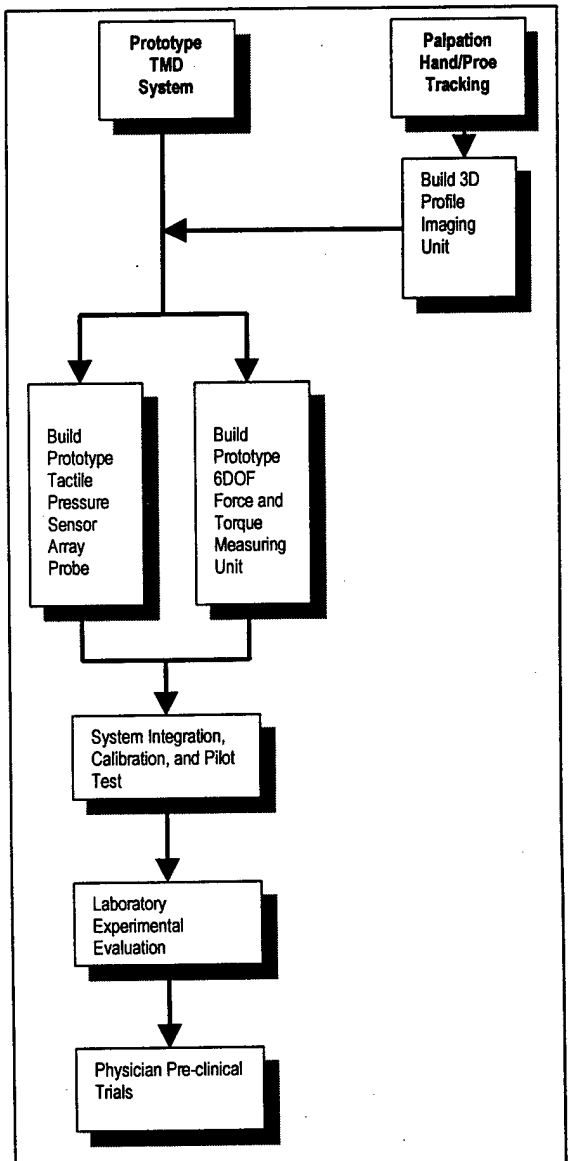



Figure 2. Steps in the development of TMD system for breast lump characterization that will demonstrate the feasibility of documenting breast tumors.

and phantom study) and the details on the signal processing for tactile feature extraction and estimation, as well as the human subject issue.

B.3 *Clinical Applications*: We discussed the TMD's application in training both clinicians and women to better perform breast examination, with a new protocol through which the examiner's sensitivity may be increased by setting a lower threshold of human tactile perception during the palpation and later supported by the TMD's sensitivity where the appropriate criteria and methods for performance comparison have been carefully considered. We have explored the TMD's function in electronic documentation as a new dimension for telemedicine, and its commercial potential.

## 3.0 Prototype System Development (Specific Aim 1)

Following the phased research plan as outlined in Figure 2, the development of a prototype TMD comprised mainly of a tactile sensor array probe (TSAP) [7,15,30], a 3D camera [6,9], a 6 degree-of-freedom (DOF) force/torque sensor [7,14,33], and a graphical user interface [7], which can provide the means to produce tactile maps of the detected breast lumps during a breast palpation. Focusing on the key tactile topology features from breast palpation such as spatial location, size and shape of the detected lesion, and the force levels used to demonstrate the palpable abnormalities, these maps can record the results of clinical physical breast examination with a set of pressure distribution profiles (i.e., images) due to detected lesion and the force sensor measurements corresponding to the applied force levels. These maps will serve as an objective documentation of palpable lesions for subsequent examinations and/or follow-up treatment assessment. Using advanced signal processing techniques, these maps will also provide new information for characterization of tumor biomechanics [8,18]. Preliminary results of simulated experiments and limited pre-clinical evaluations of the TMD prototype have pilot-tested our hypothesis and provided solid promising data showing the feasibility of the TMD in real clinical applications [7,8,9].

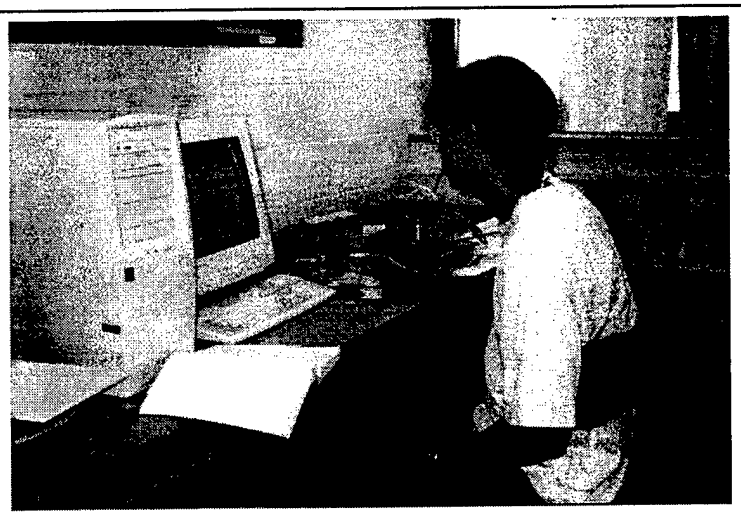


Figure 3. Prototype TMD system in the laboratory setting.

We have conducted a systematic study to adapt new tactile sensing technologies to the needs of improving physical breast examination, to gather preliminary data regarding potential clinical applications, and to advance fundamental understanding of palpation. Using the prototype TMD, we measured three key variables during palpation: the examiner's search patterns, the applied forces, and the small-scale pressure variations at the skin due to lumps, and conducted intensive experimental studies evaluate its performance. The primary objective aims that (1) new tactile mapping technology can quantitatively measure the location and applied forces in breast palpation, and the tactile features of detected breast lumps; and (2) new device can accurately characterize and document breast lumps and will improve clinicians' ability to monitor changes in lump across time. From a set of "images" of the suspect mass, a neural network supported pattern analysis program will extract the invariant properties of the lump, such as the depth and size, based on a nonlinear model of sensor-tissue interaction with hard inclusions. We also calibrated and pilot tested the prototype TMD through laboratory experiments and limited pre-clinical trial to evaluate TMD's performance in terms of reliability, validity, and safety. Our experience has shown that this novel TMD system can make it

possible for the first time to quantitatively and objectively record and characterize the processes and findings of breast palpation.

### 3.1 System Overview

The goal of this prototype TMD system is to extend the range and resolution of breast palpation methods, thus increasing palpation sensitivity and specificity (i.e, the ability to detect and characterize lumps and quantify clinically significant changes). Using 3D camera, force sensor, and tactile sensor arrays, we can create reproducible tactile maps (or images) of the palpable abnormalities in the breast. With various sizes and resolution of the tactile sensor arrays, the TMD can record the multi-foci spatial distribution of the detected lumps and the higher resolution tactile images of a particular lump.

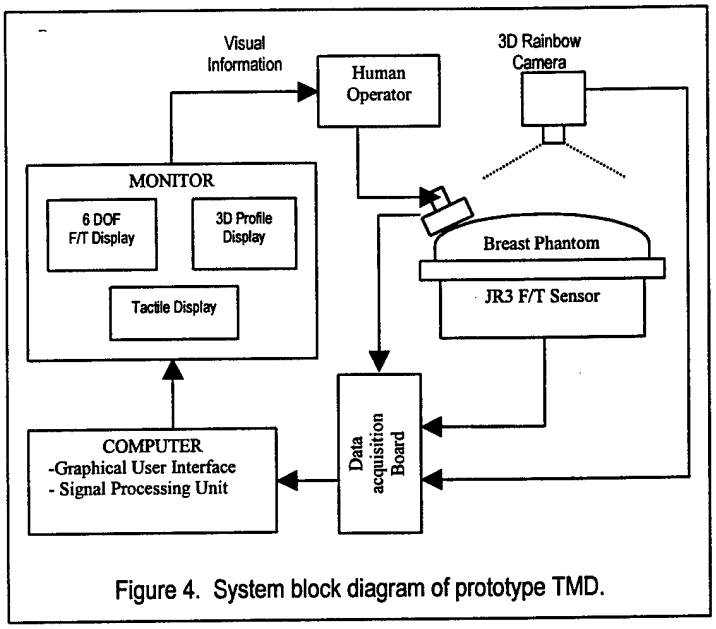


Figure 4. System block diagram of prototype TMD.

Our prototype TMD system incorporates a 3D Rainbow™ camera, a tactile sensor array probe (TSAP), a breast model with simulated lumps, a 6DOF force/torque sensor on which the breast model is mounted, and a graphical user interface (GUI). Figure 3 shows our laboratory setting of the prototype TMD system. Figure 4 shows a block diagram of the prototype *tactile mapping device* system being developed for measurement and characterization of palpable abnormalities in the breast in a laboratory setting and later in pre-clinical trial. In a typical task, upon detecting a suspicious lump with a lower tactile perception threshold, the examiner will bring the TSAP into contact with the tissue at the palpation site. For a thorough tactile mapping procedure, this involves 3D positioning the probe through the camera facing the site. The resulting pressure distribution across the probe surface is measured by a state-of-the-art tactile sensor array with associated readout electronics. Multiple tactile images with various applied force levels and torque angles will be required for an accurate lesion characterization. A computer will process and control the signals to generate appropriate output for visual display on a monitor as an interactive feedback to the on-line users or the raw data to the physician's office through a telecommunication channel. This prototype TMD system was successfully developed and have been working effectively and reliably since June 15, 1998 (about eight months) in our research site. Through extensive testing and physician's inspection (by Dr. Matthew Freedman), we believe that our prototype TMD has fully achieved the design objective [7]. Below, we describe the components of the TMD prototype in detail.

### 3.2 D Rainbow Camera

For the accurate positioning of the TSAP with the purpose of tumor localization, a novel 3D Rainbow camera is adopted in our system, which is suitable for this high-speed 3D machine vision application. Figure 5 shows the Rainbow camera acquired sample 3D range image of breast palpation procedure, where the examiner's hand/fingers, TSAP, and breast profile are clearly identified. It exploits a color light projector to illuminate the object in the scene and uses an off-the-shelve color camera to obtain a full-frame color image of the scene. The color of the projecting light with spatially

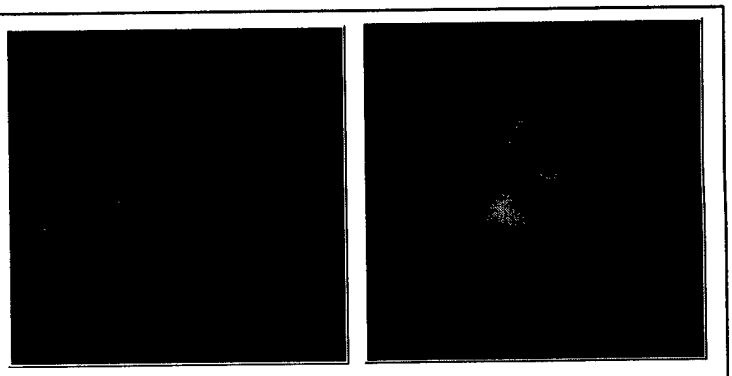


Figure 5. 3D range imaging of palpation tracking by the Rainbow camera.

continuously varying wavelength is encoded with information of the corresponding projection angle. Each pixel of the color image is associated with a unique ray through the focal point of the camera. Since the angle between camera axis and the ray is known, the resulting angle-side-angle triangulation problem can be precisely solved when the distance between the light projector and the camera is fixed. Thus, using only one camera, the full frames of 3D range images can be obtained directly at the camera frame rate (60 frames/s). The spatially varying wavelength light is generated by a white light passing through a linear variable wavelength filter.

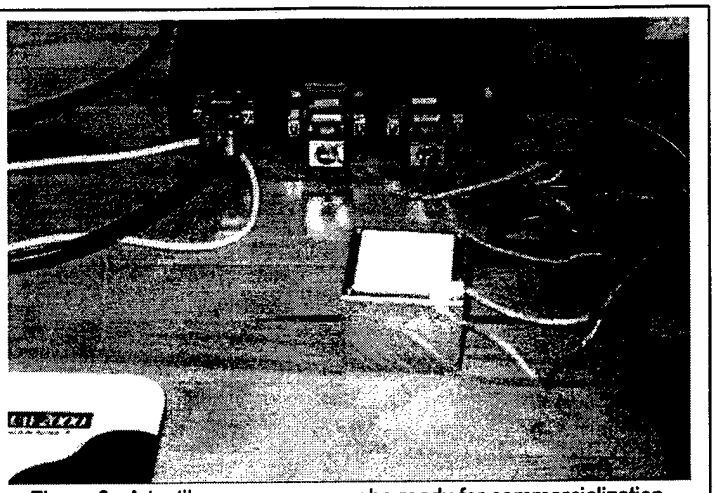


Figure 6. A tactile array sensor probe ready for commercialization.

We performed experiments to investigate the actual range accuracy and the major error contributors. The results showed that the 3D profile of test artifacts were less than 1 mm. The spatial resolution of the system is limited only by the spatial resolution of the camera optical sensing element and is currently able to provide at least 1024x1024 pixel resolution. When a palpation site is determined, multiple 3D range images will be acquired to record the site information [6,9].

### 3.3 Tactile Sensor Array Probe (TSAP)

The core component of the TMD is a high sensitive tactile sensor array probe. Figure 6 illustrates the operational setting of the specifically designed capacitive tactile sensor array used in the TSAP. A signal acquisition and processing unit with specifically designed software and hardware components were developed to generate high signal-to-noise ratio tactile readout images. Though many other types of tactile sensors were available, we have decided to use a capacitive tactile sensor in this application since it has been well-tested in surgical applications such as minimally invasive surgery and is the state-of-the-art technology in this domain [14,17,28,19]. Figure 7 shows a drawing of the actual tactile sensor array with the copper layers and the silicone rubber spacers, which is based on the state-of-the-art design by our consultant Fearing [15,30,34] and former collaborator Howe [17,28].

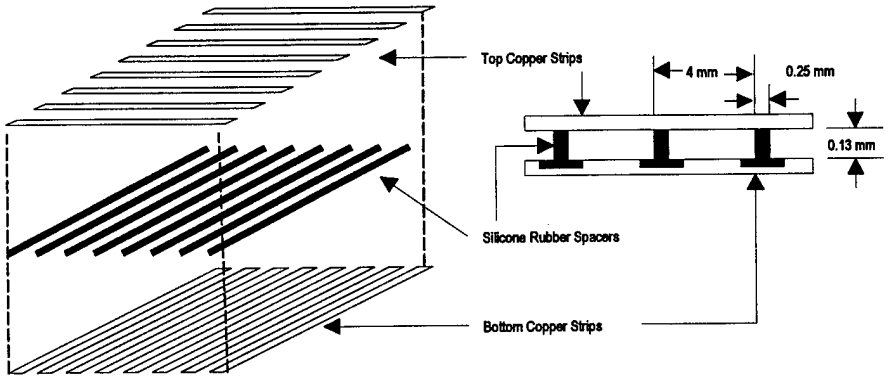



Figure 7. A drawing of a tactile array sensing.

The array is composed of two crossed layers of copper strips separated by thin strips of silicone rubber [15,17]. Each crossing area forms a capacitor, and when a force is applied onto where the strips cross, the distance between the strips decreases and the capacitance increases [28,30]. Specially designed electronics will measure the capacitance of each element and relate the capacitance change to the force applied to each element. By measuring the capacitance variations from all the elements simultaneously, we can determine the spatial distribution of pressure across the sensor array. The sensor array is made with an inexpensive photolithography and an etching process and can be easily attached to a variety of probe shapes. In this prototype specification, it is composed of an eight by eight tactile sensor array with elements that are 4 mm on a side. The sensor is

mounted on a plastic brass backing plate with a surface that has been machined into a section of a square. The backing plate is 5.08 cm on a side and the effective sensing area is 3.20 cm on a side. We decided to make the sensor flat in order to minimize inhomogeneity because the resulting pressure distribution should have a uniform overall signal to noise ratio. The tactile images will then be consistent when used for various breast/chest background textures. Other shapes of the TSAP are undergoing investigation. The actual spatial resolution of the tactile sensor array is 4 mm long where the smallest masses that we are currently interested to characterize are on the order of 1 cm in diameter. Smaller elements would increase spatial resolution at the cost of lower coverage area and low sensitivity since the capacitance is proportional to the element area [28,30]. The tactile sensor has been shielded to provide electronic insulation. We also designed two other types of TSAP, one has larger coverage area with 128x128 tactels and one has the same size as the current one but with 16x16 and/or 64x64 tactels. The purpose here is to pilot test and explore TMD's sensitivity and specificity in more broad clinical applications including treatment planing and monitoring through breast palpation.

### 3.4 Force/Torque Sensing System

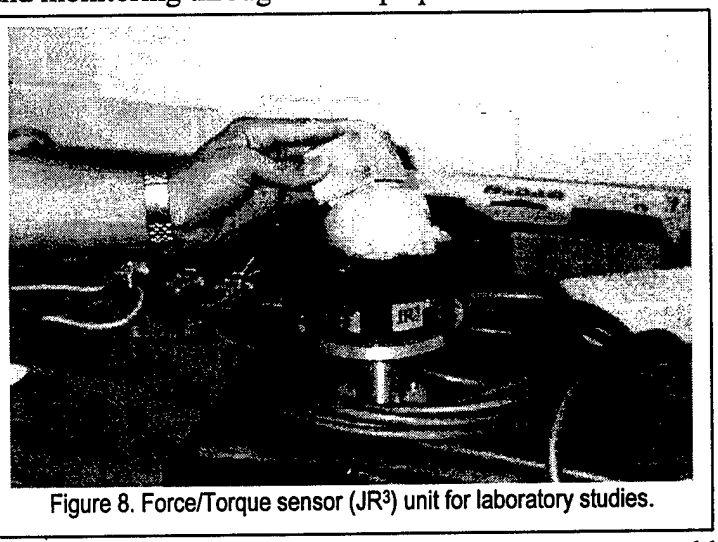


Figure 8. Force/Torque sensor ($JR^3$) unit for laboratory studies.

The relationship between the hard inclusion (i.e., lump) and the perceived tactile image from the TSAP is nonlinear and complex. In order to characterize and later extract the tactile features of the detected breast lumps, the TMD operation requires that the force/torque levels exerted by the operator (i.e., examiner) on the breast model be measured together with the corresponding tactile images. It would be ideal if a force/torque sensor were to be mounted between the wrist and the hand of the operator. Since it may be problematic and impractical to mount a force/torque sensor in such a configuration for the prototype system, we decided to mount it under a base, which the breast model is placed on. The force/torque levels acquired by the sensor in this configuration can be transformed to those exerted by the operator via proper coordinate transformation where the applied forces and angles are two important parameters. Figure 8 shows a breast model laying on a round base under which a $JR^3$ force/torque sensor is mounted. The $JR^3$ force/torque sensor mainly consists of a $JR^3$ monolithic six DOF force sensor and a $JR^3$ Intelligent Support System™, comprised of boards for signal conditioning, data acquisition and processing. A computer program written in Visual $C^{++}$ sends control command to request the $JR^3$ force/torque sensing unit to send the measurement values to the computer, including six force/torque levels and the Cartesian *x*-, *y*-, *z*-axes assigned to the base. The transmitting and receiving of data between the computer and the force/torque system is carried out through a serial port. We conducted laboratory experiments to evaluate the sensitivity of the force/torque system. The preliminary data indicated that the force measurement sensitivity is ± 0.01 lb with a maximum value of 5 lb. Through physician's pre-clinical trials (by Dr. Matthew Freedman), the sensitivity and maximum load are suitable to the desired task.

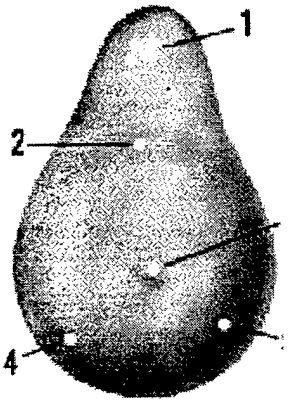



Figure 9. Breast model with simulated lumps.

## 3.5 Breast Models

The breast models used in our laboratory experiments were provided by the HEALTH EDCO, a Division of WRS Group, Inc. and the Mammatech, Co. The models were made from BIOLIKE$^{TM}$ synthetic tissue that feels just like a real breast [13,25]. Two models were used in our tests to collect preliminary data. Each of them has 5 lumps that simulate easy- and hard-to-find breast tumors with various sizes and depths at different locations. One of the models is the geriatric breast that is ideally shaped to address the special problems of older women. The geriatric model simulates the natural stretching of the tissue with age. Figure 9 shows the breast model and the distribution of simulated lumps (lesions) in the breast model. Physician's inspections have shown that the breast models are well suitable for laboratory experiment to gather preliminary data. It should be noticed that as high as 50% of breast cancers occur at the axilia area which is difficult to imaging.

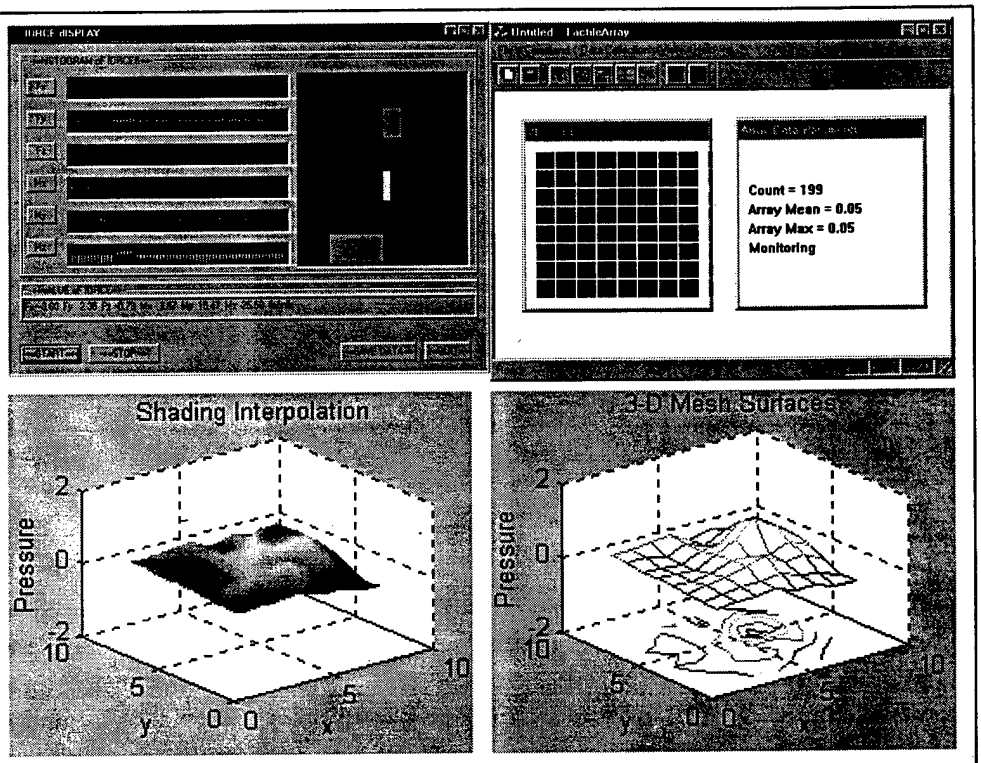



Figure 10. Graphical user interface (GUI) of the TMD prototype including 6DOF force/torque feedback (up-left), tactile imaging control menu (up-right), visual display of pressure distribution (down-left), and 3D mesh and contour map based localization (down-right).

## 3.6 Graphical User Interface

For both tactile documentation and interactive training, a graphical user interface (GUI) plays a very important role of optimizing both system and examiner's performance. Since such kind of GUI has not been available previously, we have put considerable effort to develop this function. The difficult issue here is that the GUI needs to integrate three different functions, tactile sensing, force sensing, and visual display, which were previously developed in different platform (DOS and Window95) and computer language ($C^{++}$, Assembly, and Matlab). In our prototype system, Microsoft Visual $C^{++}$ was employed to implement the GUI to visually display pertinent data of the TSAP and the force/torque sensor. Figure 10 shows the output window of the GUI that displays on-line the pressure distribution acquired by the TSAP and the time response of the six DOF force/torque applied by the examiner. The user can use a mouse to interact with the TMD functions through a menu specifically designed.

## 4.0 Applications in Documentation (Specific Aims 2)

Using the prototype TMD, we generated various tactile-images of the detected breast lumps as an objective electronic document for lesion characterization in subsequent examinations. We evaluated the performance of the TMD in this application in terms of reproducibility for subsequent exams and for different users regarding key tactile features such as pressure profiles and applied forces. The preliminary data have clearly shown the effectiveness and feasibility of tactile mapping in understanding and improving physical breast examinations for breast cancer diagnosis. Through statistical data analysis and physician's pre-clinical inspection, the reproducibility, sensitivity, and specificity were very satisfactory.

In order to demonstrate the effectiveness of the TMD system for the characterization and documentation of detected lumps, intensive experiments were conducted to pilot-test the sensitivity and reproducibility of the system in measuring the applied forces and the pressure profiles due to lumps. The primary objective here is to quantitatively acquire tactile measurements of the perceived lesions using the TMD system and to evaluate the performance of the system. In a typical experiment described below, the force/torque levels applied by the human examiner during palpation process are recorded in terms of six force/torque parameter values, i.e., Fx, Fy, Fz, Mx, My, Mz. For the tactile imaging of simulated lesions, the TSAP is used to acquire various tactile images by palpating the site after the examiner locates the lesion by initial hand palpation with a lower tactile perception threshold. Since the relationships between the tactile images and lesion characteristics are expected to be complex and nonlinear, we believe that the inverse problem (extraction of lesion characteristics from tactile images) can be solved when sufficient tactile information is acquired. As a result, for each of the lesions, after pushing the TSAP against the breast to achieve certain level of force, the examiner rotates the TSAP to five different orientations at each of which the information about the force/torque levels and tactile image are simultaneously recorded. OR1 is the initial orientation of the TSAP after being pushed by the examiner to certain level of force. OR2, OR3, OR4 and OR5 are the TSAP orientations after it is rotated forward, backward, left and right, respectively.

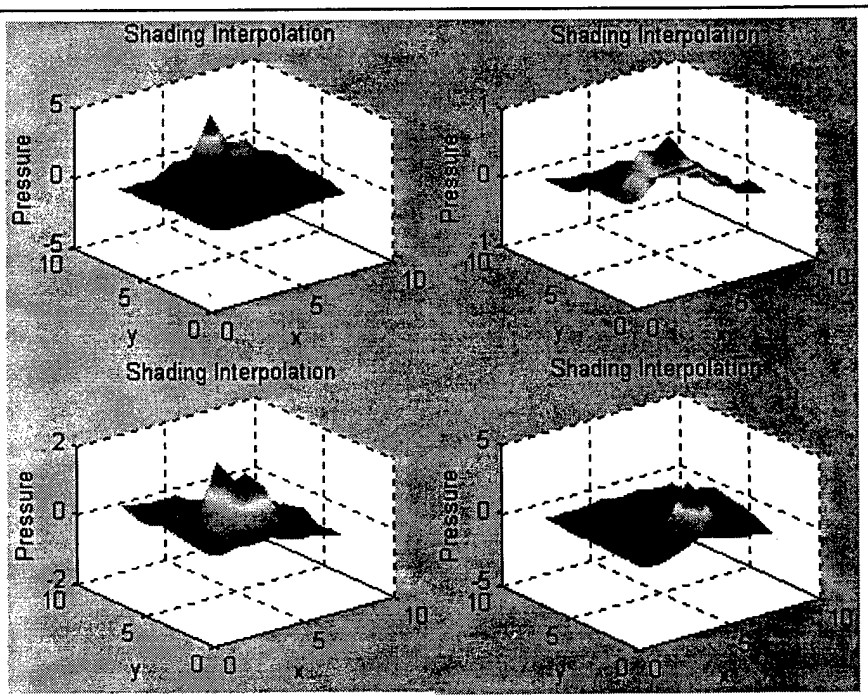



Figure 11. Multiple views of the tactile images of the detected breast lupms, using the TMD with different angles and applied forces.

We carried out the above procedure on a total of 10 simulated lesions within two types of breast models with each of them containing five lesion clusters numbered from 1 to 5. We found that the TMD had a high sensitivity for the detection of lesions #1, #4, and #5, while had a difficulty to detect lesions #2 and #3 confidently. Recall Figure 1, these data indicates that the TMD is helpful to the diagnosis and documentation of about 67% of the palpable breast cancers according to the existing statistics. We believe that these data has also supported the TMD's complementary role to the mammography since the rest of 33% breast cancers at locations

that are less detectable by TMD can be easily accessible to mammography. Therefore, during the experiment, by focusing on those suitable lesions, a total of six sets of tactile maps have been generated with each of them containing five tactile images. Figure 11 shows several typical tactile images where two representative lesions (#1 and #4) were studied. A shading interpolation of the pressure distribution measured by the TSAP was employed to achieve better visual perception. These tactile images have for the first time quantitatively displayed the tactile features of the lumps during breast palpation.

Table 1. Force/Torque measurements during the tactile image acquisition.

| Lesion | TSAP Orientation | 6DOF Force & Torque (lb/inlb) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Fx | Fy | Fz | Mx | My | Mz |
| 1 | OR1 | -0.89 | 0.44 | -0.13 | -2.58 | -10.80 | 0.50 |
| | OR2 | -2.34 | 2.50 | -0.10 | -5.26 | -22.02 | 1.59 |
| | OR3 | 1.69 | 2.96 | -0.03 | -2.28 | -10.50 | 3.57 |
| | OR4 | 3.20 | -0.38 | 0.27 | 0.40 | 0.40 | 2.09 |
| | OR5 | -1.83 | 0.38 | -0.03 | -2.38 | -9.32 | 1.99 |
| 4 | OR1 | -3.17 | 1.77 | -0.16 | 5.85 | 25.59 | -0.89 |
| | OR2 | -2.08 | 2.48 | -0.22 | 4.37 | 18.35 | 1.78 |
| | OR3 | -8.81 | -0.03 | -0.09 | 1.98 | 10.71 | 0.20 |
| | OR4 | -3.67 | -1.72 | 0.00 | 2.18 | 10.01 | 0.39 |
| | OR5 | -4.77 | 4.02 | -0.34 | 2.18 | 10.81 | 3.97 |

The Table 1 summarized the values of force/torque levels recorded from the experiments that was conducted to map Lesions #1 and #4. Before conducting the experiment on Lesion #1 and Lesion #4, we applied the same procedure on a location at which there was no lesion, as the fully controlled cases. The resulting display showed no peak. Examining the graphical displays in Figure 11, in comparison with that of the case of no lesion, we noticed that pressure peaks consistently occur in the display and a peak in the graphical display indicates the existence of a corresponding lesion. Our experience has also shown that there was a trade-off between the actual spatial resolution and the signal-to-noise ratio (SNR). Thus, further optimization of the TSAP is needed and should be conducted under the guidance of experimental data showing the best tactile characterization of various lumps. In addition, the force and torque levels that we recorded in conjunction with the tactile sensing during palpation will provide us the information about the contact location and how much force that we applied on the hard lump in the breast model. We have repeatedly conducted documentation experiments at different times, applied to different lesions, and by different users in the past six months. Our results have consistently shown the excellent reproducibility of the prototype TMD where the mean squared error (MSE) was used to measure the different between two tactile images acquired by the TMD for two identical settings. Preliminary statistical analysis also indicated the variance of the experimental data (tactile profile, force, and 3D location) was small. Figure 12 illustrates the steps in the development of TMD application in breast palpation documentation.

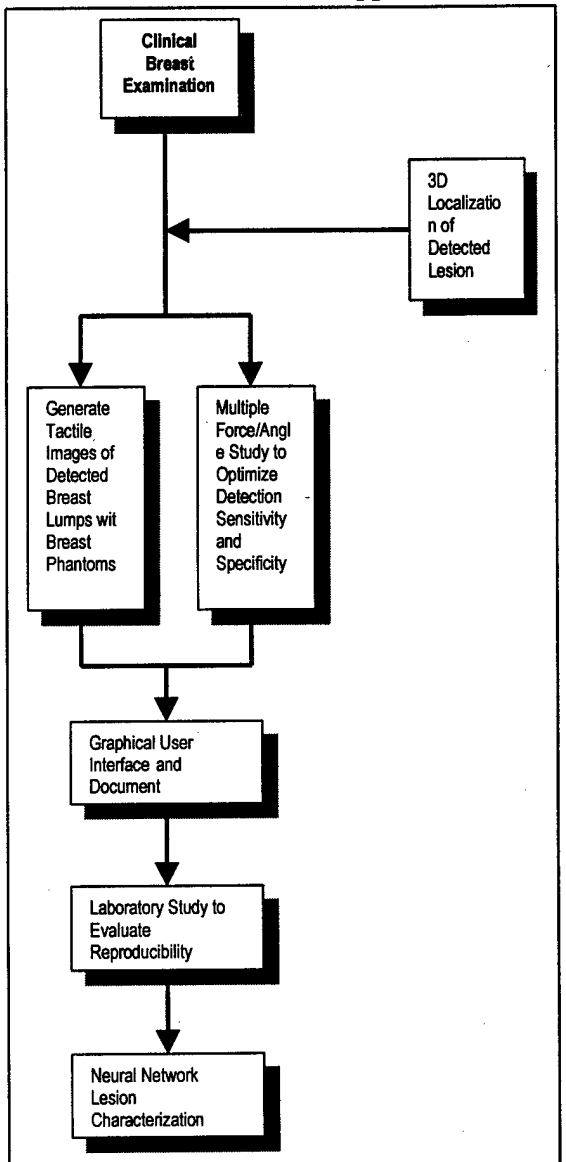



Figure 12. Protocols in the investigation of TMD in tactile feature extraction of breast pump for beast tumor diagnosis and treatment monitoring.

## 5.0 Applications in Training (Specific Aims 3)

We have studied the feasibility of TMD for training of examiners in performing physical breast examination, through the use of a computerized interactive training system, with the purpose of improving the trainees' ability in how best to search palpable abnormalities with optimal forces in detecting smaller tumors. More specifically, 3D range imaging will track the hand motion and calculate the total coverage of the palpation, and 6DOF force/torque sensor will measure the applied forces and directions. The GUI will provide the trainee a visual feedback of those measured parameters so that this interactive training program can help the trainee to understand the principal of breast palpation and adjust/improve his/her skills.

We have developed a vision-based finger motion tracking technique to gather spatial finger-position related data and have pilot tested this prototype system for breast palpation training using this technique [9]. By tracking the position of the fingers, the system can provide first-hand quantitative data about the search patterns of the palpation process. By displaying position information in real time as the palpation is performed, the system can provide for the first time the feedback so that the trainee can self check his/her search strategy and instantly know which areas have been covered. While other object tracking techniques (e.g., magnetic or

acoustic) have been proposed, vision-based tracking is considered to be the most appropriate to our task because it is the least obstructive and expensive method. Using our 3D range camera, we have adopted a model-based approach in which a 3D model of a generic human hand were employed and fitted to the specific hand shape of the user for tracking hand motion. In order to reduce the complexity of the approach, we have developed a color-assisted finger tracking step which tracks the 2D spatial positions of the three colored palpation fingernails during the training procedure. Color transform is utilized to extract color features instead of directly using the RGB values. Normalization of color attributes is used to tackle the problem of potential minor ambient lighting variations.

We have implemented a prototype palpation training program based on the proposed finger tracking and force/torque sensing approach. A small scale database was collected from the recorded expert's palpation experience. Three parameters of visual feedback are provided to the trainee: (1) search pattern, (2) applied force level, and (3) coverage area. Though our 3D camera can perform range imaging at a rate of 60 frames per second, finger tracking algorithm is not efficient enough. In this prototype setting, a 15 frames per second performance is achieved using an image size of 256x256 pixels. The system has been tested in a laboratory setting. The preliminary experimental results have proven reliable and accurate performance in tracking finger positions in 3D and the corresponding applied force levels.

## 6.0 Discussion and Conclusions

Through the research, the results have fully demonstrated the feasibility of the TMD for improving breast examination technique in diagnosis, documentation, and training. In particular, the results have shown that new tactile mapping technology can quantitatively measure the location and applied forces in breast palpation, and the tactile features of detected breast lumps; the prototype interactive training program can track finger motions and applied forces during breast palpation in which the on-line feedback can help the training to better understand the search strategy and adjust applied force level to increase the sensitivity.

In addition to the demonstration of feasibility for planning the future project, this research has also enabled many further applications for tactile mapping in breast cancer diagnosis and treatment. The tactile lesion characterization effort will contribute to our fundamental understanding of the mechanical interactions in palpation, so that optimal sensors and palpation strategies can be developed. By knowing the advantages and limitations of the sensors and the associated algorithms with respect to the detection capability and accuracy for deeper or smaller lesions, the clinical applications can be better defined. This research has extended our scope into breast cancer treatment monitoring through palpation and electronic documentation as a new dimension for telemedicine. Such a system may potentially improve outcomes by lessening the risks of ignoring cancerous tumors, and reduce costs by avoiding expensive biopsy of benign breast masses. While initially the system will be used to perform clinical breast examination, we believe that eventually it may be used in breast self-examination by women through tele-home care.

## Publications

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